



# **Response to Comments for the Water Quality Standards for Coastal and Great Lakes Recreation Waters Rule**



**Response to Comments for the Water Quality  
Standards for Coastal and Great Lakes  
Recreation Waters Rule**

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## **Introduction**

This document contains EPA's responses to the public comments received on the proposed regulations to establish water quality standards for coastal and Great Lakes recreation waters. EPA published the proposed rule on July 9, 2004 (69 FR 41720).

### ***Organization of the Comment Response Document***

This document contains excerpts from the public comment letters that were parsed into 49 broad issue categories and additional sub-issues. The Table of Contents provides the complete list of issues and sub-issues.

EPA provided a response that applies to all the excerpts within a given issue or sub-issue; the response appears at the end of the series of excerpts for each issue or sub-issue. Each issue and sub-issue begins on a new page.

## DESCRIPTION OF ISSUE CATEGORIES

Issue	Description
Tribal Waters and CWA Section 303(i)	Comments on EPA's interpretation of CWA section 303 (i) as it applies to coastal tribal waters that have not been designated for swimming, bathing, surfing, or similar water contact activities.
Analytical Methods (1-12)	Comments on analytical methods used for bacteria.
Scope of the rule	Comments that EPA needs to provide guidance on distinguishing between salt and freshwater areas in estuaries, and questions on which standards would apply.
Bacteria Criteria (1-15)	(1) Comments that EPA needs to update the 1986 criteria or that questionable science was used for the criteria. (2) Comments that EPA needs to provide explanation for needing to update criteria. (3) Comments that EPA needs to include illness rates in tables.
Implementation Guidance	Comments that EPA needs to complete and issue its Final Implementation Guidance for Ambient Water Quality Criteria for Bacteria.
Economic Burden	Comments stating that EPA's economic analyses are inadequate, or that implementation costs outweigh the environmental benefits.
California	Specific comments pertaining to the state of California.
Recreation Categories	Comments about how the Single Sample Maximum will be used (Options 1-4), comments on the 4 coastal recreation categories, and comments on the tiering process.
APA rulemaking	Comments on whether EPA should make the approved State or Territorial criteria the applicable criteria without undertaking APA rulemaking to withdraw the Federal rule?
Nationally-Based Comparison	Comments on the potential consequences of a nationally based comparison, in States with cooler climates
Rules of Applicability for Federal Criteria	Comments on whether the federal criteria should be subject to States' general rules of applicability in the same way and to the same extent as other State or Federally adopted numeric criteria for recreation waters, and comments on dilution and mixing zones.
Cruise ship	Concern about how other industries (i.e., cruise ships) will be affected by this rule.
Delaware	Specific comments pertaining to the state of Delaware.
Dual Standards	(1) Comments on how EPA should transition from existing standards to the new standards in the proposed rule, where proposed criteria apply, in addition to any other existing CWA-effective criteria for coastal recreation waters already adopted. (2) Comments on whether EPA should use dual standards to ensure that two or more uses are protected (i.e., shellfishing and primary contact recreation). (3) Comments on whether States and Territories should be allowed to phase out use of fecal coliform as a supplemental indicator.
<i>E. coli</i> and Enterococci Adoption	Comments on the progress of States' and Territories' adoption of the <i>E. coli</i> and enterococci criteria.
Effective date	Comments on the effective date of the rule.
Fecal Coliform and compliance with 303(i)	Comments on whether any State or Territory with fecal coliform as the only bacteria criterion for some or all of its coastal recreation waters is not fully compliant with 303 (i) and has been included in the proposal.
Data Supporting Use of Fecal Coliform	Comments on what type and amount of information should be sufficient for EPA to determine that fecal coliform or any other pathogen indicator is as protective of human health as the 1986 bacteria criteria.
Florida	Specific comments pertaining to the state of Florida.
Federal Register	Federal Register – editorial or opinion comments (not topic specific).
1% Illness Rate for Fresh Water (1-4)	Comments on EPA's consideration of adopting a geometric mean and SSM values for freshwater that correspond to an illness rate of 1.0% of swimmers, and EPA's acceptance of criteria associated with risk levels up to 1.0% in freshwater.
General Concerns (1-7)	<ul style="list-style-type: none"> <li>General concerns about the rule, such as setting precedent for incorrect interpretations.</li> <li>Compliance or permitting concerns.</li> <li>CSO concerns.</li> <li>Concerned about planning for new requirements.</li> <li>Concern about how other industries will be affected by this rule.</li> </ul>

Issue	Description
<i>E. coli</i> and Enterococci in the Great Lakes	Comments on <i>E. coli</i> and enterococci criteria for the Great Lakes States.
Hawaii	Specific comments pertaining to the state of Hawaii.
Louisiana	Specific comments pertaining to the state of Louisiana.
Maine	Specific comments pertaining to the state of Maine.
Mississippi	Specific comments pertaining to the state of Mississippi.
General Agreements and Disagreements	General agreement – no discussions about any of the topics. General agreement – suggestions for modifications to the rule. General disagreement – criteria are not good enough.
New Indicators, Methods, and science	(1) Comments that EPA should research new indicators and new analytical methods (even when they mention cost). (2) Suggestions on how to set standards. (3) Other sources of information (journals, etc.) for setting standards or complaining about current methods. (4) Questionable science on current methods.
New York	Specific comments pertaining to the state of New York.
Non-human Sources (1-8)	Comments on non-human sources
Public Notification	Comments on whether EPA should notify the public when bacteria criteria are exceeded, whether re-sampling will occur or not.
Ohio	Specific comments pertaining to the state of Ohio.
Oregon	Specific comments pertaining to the state of Oregon.
Pennsylvania	Specific comments pertaining to the state of Pennsylvania.
Presumption of Fishable/Swimmable	Comments on the 'rebuttal presumption of attainability'.
Extension Requests	Comments that EPA should extend the comment period.
State's and Territory's Current Standards	Comments on EPA's assessment of each State's and Territory's standard.
Compliance Schedule	Comments on the setting and use of compliance schedules to provide permitted dischargers time to meet their permit effluent limitations based on the criteria.
5-year Compliance Schedule	Comments on the limitation of five years for compliance schedules.
Seasonal uses	Comments on seasonal uses.
South Carolina	Specific comments pertaining to the state of South Carolina.
SSM (1-2)	Comments on the use of the SSM and the geometric mean, including (1) comments on the three options proposed for how to use the SSM, (2) comments on the interpretation of the phrase "as protective of human health as".
SSM-Site Specific	Comments on EPA proposing SSMs based on the 75, 82, 90, and 95 percent confidence levels and the equation to calculate site-specific SSMs.
SSM-Evaluation of States' and Territories' Standards	Comments on how EPA evaluated State and Territory SSM values and determined the existing categories and confidence intervals used by states.
State Background	(1) Background about the state's beaches program and general identification information. (2) Background about an organization's programs and general identification information.
State Flexibility	Comments that the rule language should provide states with flexibility in addressing topics within their own water quality standards.
UAA	Comments about Use Attainability Analyses.
Washington	Specific comments pertaining to the state of Washington.
Intrastate vs Interstate Basis	Comments on whether EPA should give States and Territories a choice between applying the definitions of intensity on an interstate basis or an intrastate basis.



## **Issue: 1% Illness Rate for Fresh Water #1**

**Organization Name:** Anonymous

**Document ID:** 221

**Comment ID:** 245

**Comment:**

EPA fails to pose the most fundamental question for the proposed rule which is whether the risk levels discussed are acceptable to the public. It is not clear that EPA has ever raised the issue of acceptable risk, other than for non-beach waters, explicitly in regard to the 1986 guidance for bacteria in recreational waters. The statement that the risk of gastro-enteritis from swimming in fresh water of 8/1000 and in salt water of 19/1000 has been accepted by the public is disingenuous at best since it is only after the more detailed epidemiological studies upon which EPA's 1986 guidance is based that there is now, and only in retrospect, any estimate of the risk of gastro-enteritis associated with the total/fecal coliform criteria used for decades by most jurisdictions for the regulation of swimming waters at beaches. So the discussion of raising the acceptable risk in fresh water to 10/1000 (upper limit of what is considered valid data collected on fresh water beaches) to be more in line with the 19/1000 risk in salt water at least should have been balanced by asking whether the 19/1000 risk in salt water should be lowered to 8/1000 (or lower for both) to match the now estimated fresh water risk. Certainly, such a reduction in acceptable risk is likely to mean more advisories or closures at least for salt water beaches, but it does give the public a chance to engage in an important decision--perhaps more for their children than for themselves. While states and other jurisdictions have the option of setting lower risks for their beach waters, a national discussion of the issue to explore all of the implications including relative risks would be useful.

**Organization Name:** Pennsylvania Department of Environmental Protection

**Document ID:** 233

**Comment ID:** 254

**Comment:**

We are concerned by EPA's continued reliance on the uncertain risk levels upon which the criteria are focused. The disparity between acceptable levels of risk in fresh versus marine waters is unacceptable. Persons should be able to expect similar levels of protection regardless of whether he or she swims in marine or fresh waters. Furthermore, there appears to be no more certainty than with the fecal coliform standards that the expressed risk level is correct. We urge EPA to further evaluate the effectiveness in terms of protection levels for bacteria criteria, as has been defined for other criteria, such as the risk levels of criteria for carcinogens.

**Organization Name:** People for Puget Sound

**Document ID:** 242

**Comment ID:** 35

**Comment:**

In addition, your draft rule indicates that you are considering a number of alternative approaches in several areas. As you weigh various options (including whether to increase allowable illnesses in swimmers, whether to include animal pollution when accessing compliance, etc.) we urge you to select approaches which are likely to result in more protection of water quality. Water quality problems are on the rise in Washington, particularly in relation to nonpoint pollution. There is no reason to relax standards at this stage.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 366

**Comment:**

**III. B. Paragraph 3:** Washington concurs that there is no logical basis to allow a greater illness rate in marine waters as compared to fresh waters. While we agree the risk levels should not be different between fresh and marine waters, we are confused by the fact the EPA proposal continues this disparity in risk rate. Increasing the number of allowable illnesses in freshwater to ten persons in every thousand is hardly in parity with nineteen illnesses per thousand in the marine water recommendations. No explanation is provided on why the increase in illnesses is an appropriate health policy in freshwater. There is no logical policy basis or science presented to support setting the criteria at the highest detectable illness rate that occurred in the EPA sponsored studies. It appears the EPA criteria program is focusing only on the costs of compliance when it comes to setting the bacteria criteria, but is trying to avoid acknowledging this fact in its discussions with the public and the states on this issue. We say this because the marine criteria would have to be dropped from 35 to 6/100 ml to equal the 10/1,000 illness rate suggested as acceptable for fresh water; however, the option to lower the illness risk in marine waters was not presented.

We must also note that we are very disappointed that EPA chose not to let states know that it was conducting a peer review on these controversial criteria. We would have liked to influence the questions as well as to have had an opportunity to review the material submitted to the peer review group. For over a decade we have made it clear that we want to review the data, survey procedures, and other material used to develop the national recommendations. Given our expressed interest in this topic and our prior dialogue with EPA, not informing us of this work (as well as the other studies on bacteria criteria that we have just found out indirectly that EPA is conducting) does not promote a good working relationship with our state. EPA needs to regain its focus on developing scientifically credible water quality criteria. If EPA wants more cooperation with the states, it also needs to be more open and respectful of the states concerns and rights to primacy.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 447

**Comment:**

Washington is one of many states who have expressed serious concerns about the way the EPA bather studies were conducted and evaluated, and remains skeptical that the resulting illness risk estimates are meaningful, particularly in the waters of the Pacific Northwest. Our concerns have not been addressed in our correspondence with EPA over the years, and without some confirmation studies we do not believe EPA should be modifying the national criteria recommendations based on the estimated illness rates. In addition to our concerns over the idealized use of the EPA sponsored bather studies, we are disturbed by what we view as a lack of foundation behind many of the key policy recommendations in the draft rule.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 479

**Comment:**

There was no scientific or other rational policy basis for the selection of the original risk levels, and there is none for the current proposal. A serious evaluation and public discussion is needed before establishing a federal rule that would force selected states to use criteria at levels known to cause illness in humans.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 480

**Comment:**

Additionally, there remains a significant discrepancy between the theoretic risks considered protective in marine waters versus fresh waters that has not been adequately explained. What is the basis for EPA finding it is acceptable that on average having 2 of every 100 people who immerse their heads in marine water contract serious gastroenteritis? Why would 1 in every 100 bathers becoming seriously ill be the appropriate illness rate in freshwaters? EPA should also be considering the total illness rates (minor gastroenteritis; eye, ear, nose, and throat infections; skin infections; etc.) in its calculations on acceptable health risks.

**Response:**

In today's rule, EPA has chosen to promulgate the geometric means and single sample maximums in the 1986 bacteria criteria document to comply with the requirements of the BEACH Act. No information has been provided to demonstrate that the Agency must promulgate less or more stringent criteria in order to protect the designated uses of coastal recreation waters or to comply with the requirements of the BEACH Act. EPA still believes that, based on information presented in EPA's 1986 bacteria criteria document, the criteria are fully protective of recreational uses. The illness rates in the 1986 bacteria criteria document fall below the point where epidemiological data exhibited a statistically significant difference between illness of swimmers compared to that of non-swimmers at the beaches EPA studied.

EPA developed the 1986 bacteria criteria values based on the concentrations of *E. coli* and enterococci from EPA-sponsored epidemiological studies that roughly correlated to the estimated illness rate associated with EPA's previously recommended fecal coliform criterion. EPA estimated this illness rate to be approximately 0.8% of swimmers exposed in freshwater and 1.9% of swimmers exposed in marine waters. EPA's 1986 bacteria criteria document indicates the illness rates are "only approximate" and that the Agency based the 1986 values that appear in Table 1 in the 1986 bacteria criteria document on these approximations. As a result, the illness rates associated with the 1986 bacteria criteria for marine and fresh waters are different.

The BEACH Act requires States to adopt, or EPA to promulgate, bacteria criteria as protective of human health as the 1986 bacteria criteria. Therefore, this rule adopts criteria corresponding to the illness rates in the 1986 bacteria criteria document. Today's rule does not change the risk levels because the purpose of this rulemaking is to put in place EPA's 1986 bacteria criteria for those states that have failed to do so, not to change the acceptable level of risk on which the criteria were based. EPA expects to evaluate the acceptable risk levels when EPA develops new criteria for pathogens and pathogen indicators.

## **Issue: 1% Illness Rate for Fresh Water #2**

**Organization Name:** Buckeye Florida

**Document ID:** 172

**Comment ID:** 234

**Comment:**

*Choice of illness rates for fresh water* - EPA presented data that supported an illness rate of 1.0% as protective for freshwater. Buckeye supports using scientifically based data and therefore supports this illness rate use rather than the 0.8% rate.

**Organization Name:** California Stormwater Quality Association

**Document ID:** 202

**Comment ID:** 128

**Comment:**

**Issue # 1 Adoption of Geometric Mean and Single Sample Maximum Values for Freshwater.**

USEPA is considering adopting a geometric mean and SSM values for freshwater that correspond to an illness rate of 1.0% of swimmers (i.e., 10 per 1000) in lieu of the 0.8% used in the proposed rule. The modified *E. Coli* criteria would be: Geometric mean - 206/100 ml; SSM values of 385/100 ml (75% C.L.), 489/100 ml (82% C.L.), 668/100 ml (90% C.L.), and 940/100 ml (95% C.L.). CASQA supports this approach.

**Organization Name:** Florida Department of Environmental Protection

**Document ID:** 229

**Comment ID:** 75

**Comment:**

EPA is proposing to allow States to set fresh water bacteria criteria at levels equating to illness rates of 1 percent or less. We concur with EPA's recommendation to allow States to adopt criteria believed to represent an illness rate of no greater than 1 percent of total number of swimmers.

**Organization Name:** Jeffrey A. MacDonald

**Document ID:** 177

**Comment ID:** 49

**Comment:**

**Issue** - EPA's consideration of raising the acceptable risk from 0.8% (8 illnesses per 1000 swimmers), to 1.0% (for freshwater) (p. 41725).

This small increase in acceptable risk for fresh waters does not raise the level to that which is in effect for marine waters (the acceptable risk level is 1.9% for marine waters). This increase in risk of illness of 0.2% raises the geometric mean from 126/100 mL to 206/100 mL. It is doubtful that this increase would be significant in designated swimming areas (which should be spatially distant from NPDES-permitted outfalls). In water bodies with other use designations, this change would be even less significant. Since this small increase in acceptable risk should have no effect on public health risk, I am strongly in favor of the increase in acceptable risk from 0.8% to 1.0%.



**Organization Name:** Kansas Department of Health and Environment, Division of Environment, Bureau of Water

**Document ID:** 173

**Comment ID:** 196

**Comment:**

*Proposed Criteria for Pathogen Indicators* - the proposal states "EPA cannot determine, based on the available data that relate *E. coli* and enterococci levels to illness rates, what bacteria concentration would correlate with risk levels over 1.0% in freshwater." We interpret EPA's previously published data from 1984 (EPA-600 1-84-004) as indicating bacteria levels correlate to risk levels *in excess* of 1.0%, albeit with a wider spread at the 95% confidence level. With the inherent variability in the criteria (based on the nature of the criteria's development) the widest possible spread in the confidence level should be allowed.

**Organization Name:** Milwaukee Metropolitan Sewerage District

**Document ID:** 196

**Comment ID:** 184

**Comment:**

However, if EPA has considered updated epidemiological data, we have this comment on the acceptable risk level. The small increase from 0.8% to 1.0% in acceptable risk for fresh waters does not raise the level to that which is in effect for marine waters (the acceptable risk level is 1.9% for marine waters). This increase in risk of illness of 0.2% raises the geometric mean from 126/100 mL to 206/100 mL. It is doubtful that this increase would be significant in designated swimming areas. In water bodies with other use designations, this change would be even less significant. Since this small increase in acceptable risk should have no effect on public health risk, we are strongly in favor of the increase in acceptable risk from 0.8% to 1.0%.

**Response:**

EPA appreciates the comments in support of a 1.0% illness rate being as protective of human health as the 1986 bacteria criteria for fresh water. EPA agrees that there is no significant uncertainty in the incremental health protection provided by small changes in the stringency of the criteria below the 1.0% level. Also, as described in Health Effects Criteria for Fresh Recreational Waters (EPA 600/1-84-004, August 1984), this small change is well within the confidence interval around the relationship between the pathogen indicators and the illness rate.

EPA disagrees that the interpretation of the data in the 1986 bacteria criteria document supports EPA considering risk levels in fresh water higher than 1.0% to meet the requirements of the BEACH Act. While the available data allows a correlation between *E. coli* levels and risk up to a concentration correlated to 10 illnesses, beyond that level the relationship must be extrapolated. Without evidence that the relationship holds beyond this relatively narrow window of illness rates, EPA does not find it acceptable to make that extrapolation.

## Issue: 1% Illness Rate for Fresh Water #3

**Organization Name:** NRDC, Clean Water Project

**Document ID:** 192

**Comment ID:** 204

### **Comment:**

**Pathogen Standards must be "as stringent as" EPA's 1986 criteria document adopted pursuant to Section 304(a)**

The "heart" of the proposed rule is the promulgation of standards consistent with the US EPA's current 304(a) criteria, entitled *Ambient Water Quality Criteria for Bacteria-1986*. EPA's proposed criteria define geometric mean and single sample maximum (SSM) criteria that are consistent with the agency's 1986 304(a) criteria document. These 1986 304(a) criteria are based on an "acceptable swimming associated gastroenteritis rate per 1000 swimmers" of 8 in fresh waters (.8 per cent) and 19 in marine waters (1.9 percent).

However, EPA is considering basing the acceptable rate of swimming-associated illnesses on a 1% risk level instead of the .8% risk level, asserting that this is justified because the observed data do not permit EPA to extrapolate beyond the 1% threshold. 69 Fed. Reg. at 41724-25. While NRDC appreciates the technical difficulties associated with standards development for bacteria, NRDC believes that the standards promulgated should be based upon the .8 percent acceptable risk level. If EPA were to permit standards to be based on a 1% acceptable illness rate, this standard would, statistically speaking, allow for a 25% greater number of swimming-associated illnesses. Such a standard would thus not be "as protective of human health" as EPA's 1986 304(a) criteria document, and thus would not be consistent with the requirements of Section 303(i) of the Clean Water Act. Therefore, EPA should promulgate criteria based on the .8% acceptable illness rate, because any higher acceptable risk levels would not be "as protective of human health" as the agency's 1986 304(a) criteria and thus would not be consistent with the requirements of the CWA as modified by the BEACH Act.

**Organization Name:** New Jersey Department of Environmental Protection

**Document ID:** 178

**Comment ID:** 16

### **Comment:**

**Use of a 1% illness rate for freshwaters rather than the currently used 0.8%**

Raising the acceptable illness rate from 0.8% to 1% for freshwaters might make sense if the illness rate for marine waters was simultaneously reduced from 1.9% to 1%. However, such a reduction in illness rate for marine waters would result in an acceptable Enterococcus geometric mean (Gm) value of 7 per 100 ml rather than the current 35 per 100-ml value. A Gm of 7 and its associated single sample maximum numbers are not generally achievable values from a water quality compliance standpoint. Thus, the currently used illness rate value for freshwaters should probably remain as is since the associated *E. coli* Gm value is "equivalent" to the previously used fecal coliform Gm value of 200 per 100 ml. States could be accused of "backsliding" if the acceptable freshwater indicator Gm values were raised as a result of arbitrarily raising the acceptable illness rate.

**Organization Name:** Pennsylvania Department of Environmental Protection  
**Document ID:** 233  
**Comment ID:** 264

**Comment:**

The proposed criteria tables contained in 40 CFR 131.41(c) should contain additional geometric mean and SSM values corresponding to the other relative risk levels (illness rates) that were contained in the Draft Implementation Guidance previously being developed by EPA.

**Organization Name:** State of Washington Department of Ecology  
**Document ID:** 243  
**Comment ID:** 367

**Comment:**

For the record, we oppose increasing the risk level in fresh waters. We believe a concentration around 100 (e.g., 126 *E. coli*) is widely attainable and better associated with statistical increases in illness rates (both total and HCGI). The associated criteria shift would additionally be based on what we believe are marginal quality studies and faulty statistical inference.

**Organization Name:** State of Washington Department of Ecology  
**Document ID:** 243  
**Comment ID:** 462

**Comment:**

We do not agree that it is appropriate to increase the theoretic illness rate in fresh waters. The statistical design of the EPA studies was poor and too few data points were used to generate the incidence rate curve. Further, many of the relationships between fecal coliform and *E. coli* indicators found in the east coast studies appears invalid in our state's waters. For these reasons, the illness rate curve is almost certainly incorrect, and is unsuitable for making public health decisions on an illness rate basis.

**Response:**

See the preamble to today's rule, in particular section V.A., How Did EPA Decide Which States and Territories to Include in Today's Rule?

Today's rule establishes water quality criteria for fresh waters based on a risk level of 0.8% for those States covered by the rule. In evaluating a State's water quality standards EPA disagrees that it should only consider an illness rate of 0.8% to be as protective of human health as the 1986 bacteria criteria document. To do so would suggest that there is significant uncertainty in the incremental health protection provided by small changes in the stringency of the criteria below the 1.0% level. More importantly, as explained in the proposal, EPA does not see any a priori reason to require a greater level of protection for freshwaters than for marine waters, which account for the vast majority of swimming days in coastal recreation waters subject to section 303(i) of the Clean Water Act. See the proposed rule (69 FR 41724) for further discussion of EPA's reasoning.

EPA acknowledges the concern that States would be accused of "backsliding" on its water quality standards by adopting bacteria criteria associated with a 1% risk level rather than the 0.8% risk level. However, nothing in today's rule suggests that States should adopt water quality standards for bacteria that are less stringent than those standards already in effect. As discussed in the

previous paragraph, EPA does not consider the small difference between 0.8% and 1.0% illnesses to represent significant uncertainty in the incremental health protection.

EPA acknowledges that disinfection technology can achieve levels of bacteria lower than the 1986 bacteria criteria. However, EPA does not consider attainability when developing criteria, but bases its criteria on the available scientific information regarding the levels of pathogens and pathogen indicators necessary for protection of human health. EPA does consider attainability when developed technology-based effluent requirements.

EPA acknowledges the comment that the fresh water criteria were not based on field studies in the west. However, EPA points out that the fresh water criteria in the rule do not apply outside of the Great Lakes. The scope of the rule is only for coastal and Great Lakes waters, and the fresh water criteria in the rule only apply to the Great Lakes in today's rule.

EPA declines to publish all the potential combinations and permutations of criteria that States may adopt to comply with the BEACH Act. To do so is outside the scope of today's rule which promulgates bacteria criteria for those States and Territories that have not yet adopted water quality criteria and standards as protective of human health as EPA's 1986 bacteria criteria document.

## Issue: 1% Illness Rate for Fresh Water #4

**Organization Name:** Milwaukee Metropolitan Sewerage District

**Document ID:** 196

**Comment ID:** 183

**Comment:**

With respect to **identifying an acceptable risk level**, we understand that EPA has been advised by its peer review panel not extrapolate beyond the 1.0% risk level, based on the observed data. However, we are not clear on what the "observed data" are. Did EPA review and analyze only the data available at the time the 1986 criteria were published, or was the epidemiological data updated? This is not clear from the preamble to the proposed rule. We strongly urge that all available data be reviewed, including that which has been gathered since the 1986 process; and we are interested in knowing what data were reviewed. Without that information, it is not possible to comment in a meaningful way on the EPA choice of illness rate for calculating the criteria.

**Organization Name:** Pennsylvania Department of Environmental Protection

**Document ID:** 233

**Comment ID:** 253

**Comment:**

The full details of the *External Peer Review of EPA Analysis of Epidemiological Data from EPA Bacteriological Studies, February 2004* have not been made available for our review, and therefore, we have been unable to adequately assess the statements and conclusions drawn from that review, especially as it relates to EPA's decision to limit the relative risk level to 1.0 % (Pg. 41725). This Peer Review and related issues were to be further discussed / explored in the Draft Implementation Guidance that now seems to be abandoned.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 478

**Comment:**

We must also note that we are very disappointed that EPA chose not to let states know that it was conducting a peer review on these controversial criteria. We would have liked to influence the questions as well as to have had an opportunity to review the material submitted to the peer review group. For over a decade we have made it clear that we want to review the data, survey procedures, and other material used to develop the national recommendations. Given our expressed interest in this topic and our prior dialogue with EPA, not informing us of this work (as well as the other studies on bacteria criteria that we have just found out indirectly that EPA is conducting) does not promote a good working relationship with our state. EPA needs to regain its focus on developing scientifically credible water quality criteria. If EPA wants more cooperation with the states, it also needs to be more open and respectful of the states concerns and rights to primacy.

**Response:**

As explained in the proposal to the rule (69 FR 41724-41725), EPA conducted an external peer review of EPA's analysis of the epidemiological data from EPA's bacteriological studies on which the 1986 bacteria criteria document is based. EPA provided the reviewers three documents to assist them in their review: *Ambient Water Quality Criteria for Bacteria* - 1986 (Docket OW-

2004-0010-0003), *Health Effects Criteria for Fresh Recreational Waters* (Docket OW-2004-0010-0004), and *Health Effects Criteria for Marine Recreational Waters* (Docket OW-2004-0010-0005). EPA asked the peer reviewers to consider the data upon which EPA based the 1986 bacteria criteria document so that this information could help inform EPA in determining the bounds within which a State's water quality criteria could be considered as protective of human health as EPA's 1986 bacteria criteria. EPA provided this peer review in the docket for the proposed rule (Docket OW-2004-0010-0013), and it was available to all the commenters. However, one reviewer did consider additional information in his review; this information is included in the peer review document.

## Issue: 5-Year Compliance Schedule

**Organization Name:** Milwaukee Metropolitan Sewerage District

**Document ID:** 196

**Comment ID:** 188

**Comment:**

**Longer duration compliance schedules** (*i.e.*, longer than the proposed maximum of 5 years) will absolutely be necessary and should be allowed for certain permit activities that will require extensive studies and construction activities, *e.g.*, long term control plans associated with combined sewer overflows, and storm water systems under permit.

**Organization Name:** NRDC, Clean Water Project

**Document ID:** 192

**Comment ID:** 206

**Comment:**

### **Compliance Schedules & Enforcement**

The EPA proposed rule, as applied to those states that have not adopted regulations that are "in effect for CWA purposes authorizing compliance schedules for [Water Quality Based Effluent Limits] WQBELs," gives such states the option to include such compliance schedules. EPA also limits compliance schedules to five years, but solicits comments on whether "the limitation of five years for compliance schedules is reasonable or should longer schedules be allowed for certain permit activities that require extensive studies and construction activities." NRDC believes that five years is an ample maximum for compliance schedules and that longer compliance schedules should be disallowed. NRDC's opposition to compliance schedules longer than 5 years is based on its understanding of the requirements of the Clean Water Act, which limits the term of every permit to 5 years and requires every permit to require compliance with water quality based and technology based standards. 33 U.S.C. 1342(a) & (b)(1)(B). Compliance schedules that exceed 5 years are, therefore, illegal. In addition, these standards should be no surprise to any NPDES permitting authority or permittee. They are based on water quality criteria that have been in place since 1986, *i.e.*, 18 years, and the requirement that states adopt them has been in federal law since the BEACH Act was passed in December of 2000. Five additional years is long enough to get them implemented.

**Organization Name:** Pennsylvania Department of Environmental Protection

**Document ID:** 233

**Comment ID:** 262

**Comment:**

States should be given the option to set compliance schedules to meet more stringent limits based on these new criteria as part of their water quality standards or as part of their implementation regulations. We generally agree that compliance schedules should not be extended for an indefinite time or be automatically renewed, but compliance schedules for existing or expanding facilities may require more than the typical 5-year maximum limit where certain activities will require extensive studies or construction activities. If more than 5 years is required to meet the more stringent limits, however, the discharger must request the longer compliance schedule or an extension with the provision that the discharger also provide a long-term control plan with annual/periodic reporting requirements, which also contains specific milestones and compliance goals.

**Organization Name:** State of Ohio Environmental Protection Agency

**Document ID:** 238

**Comment ID:** 134

**Comment:**

Also, the provisions for schedules up to five years, the requirements for interim steps and dates, and the ability to write a schedule that exceeds the term of an NPDES permit provide important flexibility to the permit writer. We agree that five years should not be used as a default duration for a schedule and believe that, in most cases, three year schedules should be adequate.

**Organization Name:** The CSO Partnership

**Document ID:** 197

**Comment ID:** 414

**Comment:**

**EPA Cannot Impose an Arbitrary Limit on Compliance Schedules.**

Schedules are a State Prerogative. We object to EPA's propose limitation of compliance schedules to a maximum of five years. EPA offers absolutely no justification for this arbitrary limitation. The Clean Water Act does not authorize EPA to impose limits on state-authorized compliance schedules. The extent of compliance schedules is purely a State prerogative in this circumstance. EPA could recommend compliance schedules of up to five years for existing dischargers, but cannot legally limit compliance schedules to five years to the extent a State's water quality standards would allow a longer period.

CSO Discharges Warrant Special Acknowledgement. We believe that Section 402(q) of the CWA authorizes long-term implementation schedules for CSO discharges and that such discharges do not have to comply with water quality standards until after the implementation of approved long-term CSO control plans. This means that compliance schedules for bacteria are not necessary or applicable to CSO discharges. To the extent EPA does not embrace this interpretation, at a minimum this rule should specify that:

"For CSO impacted waters the schedule of implementation for the water quality standards shall match the approved long term control plan."

**Response:**

See the preamble to today's rule, in particular section IV.D., Compliance Schedules.



## **Issue: *E. coli* and Enterococci in the Great Lakes**

**Organization Name:** Buckeye Florida

**Document ID:** 172

**Comment ID:** 241

**Comment:**

*Choice of Pathogen Indicator for Fresh Coastal Recreation Waters* - Although this is for the Great Lakes States with coastal fresh waters, it has the potential to be applied further for other fresh waters. Therefore, Buckeye supports maximum flexibility given to the States/Territories by allowing either *E. coli* or enterococci.

**Organization Name:** Massachusetts Department of Environmental Protection

**Document ID:** 208

**Comment ID:** 64

**Comment:**

EPA should leave open to the states the option of which indicator and risk level to use for fresh waters.

**Organization Name:** New York State Department of Environmental Conservation

**Document ID:** 218

**Comment ID:** 84

**Comment:**

Selection of Pathogen Indicator for Fresh Coastal Recreation Waters.

New York formally requests that USEPA's final rule includes both *E. coli* and enterococci values for New York's coastal freshwaters (Great Lakes), and allows the State to select either of these indicators at the time of implementation. Effective June 23, 2004, the New York State Department of Health adopted a regulation that added both *E. coli* and enterococci as criteria for freshwater bathing beaches. New York is in the process of determining which indicator will be most appropriate for implementation of the BEACH Act in ambient coastal freshwaters.

**Organization Name:** Pennsylvania Department of Environmental Protection

**Document ID:** 233

**Comment ID:** 259

**Comment:**

EPA should promulgate the final rule allowing Great Lakes States to choose either *E. coli* or enterococci criteria as the indicator to apply to its coastal recreation waters at the time of implementation.

**Response:**

See the preamble to today's rule, in particular section IV.B.1., Selection of Pathogen Indicator.

## Issue: APA Rulemaking

**Organization Name:** Buckeye Florida

**Document ID:** 172

**Comment ID:** 436

**Comment:**

Buckeye further supports rule language that would make EPA promulgated criteria no longer applicable once a State or Territory have their own EPA approved criteria in place.

**Organization Name:** California Regional Water Quality Control Board, San Diego Region

**Document ID:** 199

**Comment ID:** 119

**Comment:**

**Applies in Addition to any State/Territory Criteria**

1. "...EPA is proposing rule language which would make the EPA-approved bacteria criteria in State or Territorial water quality standards effective for CWA purposes upon their approval such that EPA's promulgated criteria would no longer apply."

The Regional Board agrees with this proposal to make EPA-approved bacteria criteria effective in a more expeditious manner.

**Organization Name:** Department of Environmental Services City and County of Honolulu

**Document ID:** 235

**Comment ID:** 301

**Comment:**

Section 131.41(d)(1)

We concur that EPA-approved WQS criteria to address BEACH Act requirements should be the applicable criteria without first undertaking APA rulemaking to withdraw the Federal rule. Delays in APA rulemaking would require affected dischargers to comply with Federal criteria and expose them unnecessarily.

**Organization Name:** Kansas Department of Health and Environment, Division of Environment, Bureau of Water

**Document ID:** 173

**Comment ID:** 198

**Comment:**

**Applies in Addition to any State/Territory Criteria**

EPA solicits comment on a proposal that State criteria become immediately enforceable upon approval by EPA - prior to a Federal Register notice of removal of the promulgated federal criteria. If this proposal is legal, we are strongly supportive. We would also encourage this process be utilized for all federal promulgations.

**Organization Name:** Massachusetts Department of Environmental Protection  
**Document ID:** 208  
**Comment ID:** 66

**Comment:**

EPA should make the process for states to adopt their own criteria as easy administratively as possible and also without prejudice if they differ from the version adopted for the state by EPA, so long as the criteria selected by the state is consistent with the national guidance.

**Organization Name:** Pennsylvania Department of Environmental Protection  
**Document ID:** 233  
**Comment ID:** 265

**Comment:**

We soundly endorse the proposal in 40 CFR 131.41(d)(1) that EPA promulgated criteria for a state would no longer apply when EPA approves a state's criteria. Waiting for EPA to formally remove a promulgation through subsequent rulemaking according to requirements of the Administrative Procedure Act is a long process and presents complications in understanding and implementing a program in the interim. We encourage EPA to adopt this provision in this regulation and to consider it in future promulgations, as well.

**Organization Name:** State of Alaska Department of Environmental Conservation/Division of Water  
**Document ID:** 175  
**Comment ID:** 157

**Comment:**

**Applies in Addition to any State/Territory Criteria.**

This part includes a discussion of the proposed rule language at 40 CFR 131.41(d) that provides for immediate application of state criteria in lieu of the EPA-promulgated criteria immediately upon EPA approval of the state criteria. The State of Alaska supports this provision. This will reduce the amount of time that both state and EPA criteria apply, thus reducing the potential for confusion or needless duplication.

**Organization Name:** State of Hawaii Department of Health/Environmental Health Administration  
**Document ID:** 195  
**Comment ID:** 392

**Comment:**

**Later State Rules:**

We strongly support the provision that State Rules adopted after the these proposed EPA rules or any adopted EPA Rules become effective after EPA approval, without the need for amendment of the federal regulation, as long as Hawaii's criteria are as protective of human health as the EPA's 1986 fecal indicator criteria for coastal recreational waters. (Clean Water Act, Section 303 (i)). In general, DOH prefers that the State adopt its own rules for Hawaii, consistent with federal law. Furthermore, DOH has pending amendments on the indicator bacteria standards for coastal recreational waters currently in the Hawaii Administrative Rule, Chapter 11-54, Water Quality

Standards (WQS), and has completed public hearings on some amendments to the chapter. DOH also intends further work on indicator bacteria issues.

**Organization Name:** Wisconsin Department of Natural Resources

**Document ID:** 176

**Comment ID:** 113

**Comment:**

The Section agrees with EPA in Section III. C.1. Wisconsin is in the process of adopting water quality standards to be as protective as EPA's 1986 bacteria criteria. We agree that EPA should propose rule language that would make EPA-approved bacteria criteria effective for CWA purposes upon their approval such that EPA's promulgated criteria would no longer apply. EPA's current proposals for recreational water criteria do not take into account applicable State law or other State specific issues such as seasonal recreation or seasonal disinfection requirements.

**Response:**

See the preamble to today's rule, in particular section IV.C., Applicability of Today's Rule.

This rule establishes water quality standards for waters that are already designated for swimming, bathing, surfing, and similar water contact activities. It does not establish uses, or subcategories of uses, for any State or Territory covered by the rule. Today's rule does not change States' and Territories' ability to adopt seasonal uses for their waters, including Great Lakes and marine waters. If a State or Territory has adopted a seasonal recreation use, the promulgated criteria only apply during the periods in the year where the water quality standards designate the recreational use. EPA notes that the rule at 40 CFR 131.41(d)(2) makes the promulgated criteria subject to a State's or Territory's general rules of applicability and thus today's rule does not change any requirements for disinfection that may be in those State or Territorial rules. Therefore, there is no need for this rule to take into account seasonal recreational uses or seasonal disinfection requirements.

EPA agrees with the commenters that the process to remove states from the rule should be as administratively easy as possible. In light of this, EPA is finalizing the provision offered in the proposed rule whereby states' water quality standards will be effective immediately upon EPA approval. EPA will not need to formally amend the Code of Federal Regulations to remove the application of the federal criteria to states. However, EPA will still take this action to ensure that the Code of Federal Regulations reflects EPA's decision to approve the state standards.

Although this provision is intended to ease the administrative burden on states and territories, it does not remove the responsibility for states and territories to develop water quality standards and criteria for their coastal recreation waters that are as protective of human health as EPA's 1986 bacteria criteria.

## **Issue: Analytical Methods 1**

**Organization Name:** American Society for Microbiology

**Document ID:** 162

**Comment ID:** 47

**Comment:**

The ASM offers the following recommendations in an effort to address some of the issues found in the proposed rule.

**ISSUE:**

Because the proposed rule uses bacteriological methods that require 24 or more hours to provide results, determining fecal contamination and the actions they would trigger, such as beach postings or closures, potentially occur after the contamination subsided. Furthermore, rainfall is well known to greatly increase contamination levels in surface waters and is used as a basis for closing shell-fishing waters without waiting for bacteriological results.

**SOLUTION:**

The EPA should embark on research and demonstration efforts to develop and evaluate rapid microbial methods, the use of rainfall data and other management tools (e.g., other geohydrographical data) as predictive tools for making management decisions about beaches.

Serious human health risks can arise from exposure to fecal contamination in recreational waters. Therefore, the ASM encourages the EPA to fully evaluate relationships between indicator species and health risks, and to incorporate a more complete understanding of indicator species ecology, microbial source tracking and sample statistics to provide adequate public health safety in coastal and Great Lakes recreational waters.

**Organization Name:** NRDC, Clean Water Project

**Document ID:** 192

**Comment ID:** 442

**Comment:**

NRDC also encourages EPA to accelerate ongoing research into beachwater testing methods for pathogens that can provide immediate results. Currently available tests usually take 24 hours or longer to provide results. Faster testing methods would improve public safety by minimizing the risk of unwitting public exposure to waterborne pathogens.

**Response:**

EPA is currently conducting an epidemiological study whose final goal is new risk-based water quality guidelines and rapid methods for recreational waters. The study utilizes a rapid genetic method which produces quantitative results. These tests, when validated, should be able to produce more timely information regarding fecal contamination of water bodies, which would address rainfall and other sudden influxes of contamination. EPA is also working on microbial source tracking methods and anticipates issuing a guide document on this topic in 2005.

## Issue: Analytical Methods 2

**Organization Name:** Jeffrey A. MacDonald

**Document ID:** 177

**Comment ID:** 48

**Comment:**

I support research that will develop microbial indicators that are more protective of public health than are the current indicators. Before these can be implemented, however, reasonably facile and inexpensive quantitative methods must be developed. Great caution must be exercised when changing the indicator by which microbial risk is monitored. Changing the indicators utilized has great impacts (monetary and otherwise) upon the regulated and monitoring communities.

**Issue** - *E. coli* is a subset of the fecal coliform group. Since *E. coli* is a subset of the fecal coliform group, one would expect higher levels of fecal coliforms (FC), relative to *E. coli*, in a sample. Data from a number of Wisconsin wastewater facilities has shown, however, that if a wastewater treatment facility uses chlorine as a disinfectant, and quantifies FC by membrane filtration, and *E. coli* using an MPN (Most Probable Number) method (such as the defined substrate system that employs Colilert reagent), most of the time the *E. coli* value will be greater than the FC value. This is a result of the relatively poor recovery of chlorine-stressed organisms by the MF method, as compared to MPN methods. Recovery of stressed organisms is important because chlorine-stressed pathogenic bacteria have been shown to be capable of recovering their infectivity following chlorination. Development of the 1986 bacteria criteria was based on enumeration of *E. coli* in non-chlorinated freshwaters by a membrane filtration method. Enumeration of *E. coli* by an MPN method, while improving recovery, may place a facility at a disadvantage (regarding compliance) relative to a facility that uses an MF method.

**Comment** - It is my recommendation that EPA create a method specific limit for *E. coli* to remove the inherent problem in *E. coli* monitoring when MF and MPN methods are both deemed appropriate, or in some other manner address this situation. Side-by-side analyses have shown that MF and MPN methods do not recover similar fractions of the bacteria present (MF does a poor job of recovering stressed fecal coliforms and *E. coli*). Use of an MPN method would be a conservative approach - this would serve to make the rule more protective. The increased resistance of viruses, *Giardia* cysts, and *Cryptosporidium* oocysts to chlorination, relative to *E. coli*, also makes this conservative approach appropriate. It is of critical importance to err on the side of public health in this matter - since the indicator that is proposed is a vegetative bacterium (and quite susceptible to chlorine and other disinfectants) every effort should be made to maximize its recovery from wastewater effluents.

**Organization Name:** Milwaukee Metropolitan Sewerage District

**Document ID:** 196

**Comment ID:** 187

**Comment:**

**Choice of Pathogen Indicator:**

MMSD supports the use of *E. coli* as pathogen indicator. *E. coli* is a subset of the fecal coliform group. Since *E. coli* is a subset of the fecal coliform group, one would expect higher levels of fecal coliforms (FC), relative to *E. coli*, in a sample. Data from a number of Wisconsin wastewater facilities has shown, however, that if a wastewater treatment facility uses chlorine as a disinfectant, and quantifies FC by membrane filtration, and *E. coli* using an MPN (Most Probable

Number) method (such as the defined substrate system that employs Colilert reagent), most of the time the *E. coli* value will be greater than the FC value. This is a result of the relatively poor recovery of chlorine-stressed organisms by the MF method, as compared to MPN methods. Recovery of stressed organisms is important because chlorine-stressed pathogenic bacteria have been shown to be capable of recovering their infectivity following chlorination. Development of the 1986 bacteria criteria was based on enumeration of *E. coli* in non-chlorinated freshwaters by a membrane filtration method. Enumeration of *E. coli* by an MPN method, while improving recovery, may place a facility at a disadvantage relative to a facility that uses an MF method.

MMSD recommends that EPA consider the creation of a method specific limit for *E. coli* to remove the inherent problem in *E. coli* monitoring when MF and MPN methods are both deemed appropriate, or in some other manner address this situation. Use of an MPN method would be a conservative approach - this would serve to make the rule more protective. The increased resistance of viruses, *Giardia* cysts, and *Cryptosporidium* oocysts to chlorination, relative to *E. coli*, also makes this conservative approach appropriate.

**Response:**

As indicated in Table 3 of today's rule, the following membrane filtration procedures may be used for the determination of *E. coli* in fresh recreational waters: Methods 1103.1, 1603, and 1604 or equivalent. (It should be noted that the method numbers in footnote a for Tables 2 and 3 in the July 9, 2004 FR proposal for *E. coli* and enterococci, respectively, should be reversed - the method numbers for the *E. coli* test were in Table 3, footnote a.) As a result, method equivalency would have to be demonstrated prior to using another procedure, such as an MPN method. It should also be noted that Methods 1103.1 and 1603 have been subjected to interlaboratory validation in an assortment of disinfected wastewaters, including wastewater disinfected by chlorination, and final reports will be available in late 2004.

## Issue: Analytical Methods 3

**Organization Name:** State of Maine Department of Environmental Protection

**Document ID:** 240

**Comment ID:** 97

**Comment:**

**Closing comment**

The MEDEP would like to close with the recommendation that the EPA actively pursue wholly new pathogen criteria and test methods. While enterococci and *E. coli* tests provide improvements over the old fecal coliform and total coliform test methods, for several reasons they are still poor indicators of swimmer risk and inefficient. First, bacteria do not occur as a homogeneous concentration, thus, the tests are notoriously variable in the results they produce. Secondly, while the tests indicate unspecified fecal contamination, they provide no information on source or relationship to actual pathogen presence or concentration. Third, the tests are too slow to provide timely exposure information for health advisory-based decision-making. Results are received well after exposures have occurred. While this rule may provide a national standard, it should not be construed as providing a satisfactory method for swimmer protection.

**Response:**

See the response to comment IDs 47 and 442.

In addition, EPA recognizes that bacteria are not necessarily distributed in a homogenous fashion, hence the inclusion of criteria for the geometric mean, in addition to the single sample maximum. Some recent studies suggest there may be some risk posed to humans as a result of exposure to non-human fecal contamination, particularly those animal sources with which humans regularly come into contact, i.e., livestock and other domestic animals. EPA recognizes that the indicators *E. coli* and enterococci are not specific to human fecal contamination. However, since animal sources may result in human illness, the use of these indicators for fecal contamination in general provides a higher level of human health protection.



## Issue: Analytical Methods 4

**Organization Name:** American Forest and Paper Association

**Document ID:** 191

**Comment ID:** 194

**Comment:**

In addition, AF&PA echoes NCASI's concern about the lack of validation of these indicator methods on pulp and paper effluent matrices and agrees that EPA should alert the States that methods for analyzing effluents have not been validated for wastewater matrices prior to charging the States with implementing the criteria by incorporating limits in NPDES permits.

**Organization Name:** Fraser Papers

**Document ID:** 165

**Comment ID:** 107

**Comment:**

Fraser Papers Encourages EPA to Explore the Validation Status of Analysis Methods to be Employed to Implement the Criteria

Although the agency is proposing these bacteriological criteria for ambient waters, they will be implemented in the context of effluent limitations in NPDES permits. The fact that methods for analyzing the effluents have not been validated for wastewater matrices should be made known to the States, so that the criteria will not be implemented until this has taken place. Also, since pulp and paper mill effluents will be analyzed for the substances, they should be included in the method validation work.

By way of background, it is our understanding that EPA has not completed validation of the new membrane filter methods for the enumeration of *E. Coli* 1103, 1603, 1604, and enterococci 1106, 1600 in wastewater matrices, although these methods were proposed in an April 6, 2004 Federal Register notice. EPA's ongoing validation does not include pulp and paper effluent matrices. EPA has indicated that these methods are currently only promulgated for use in ambient streams, and these methods were used to establish the proposed ambient water quality criteria cited in the proposal. Standard Method 9221F, a multi tube test also proposed in this same Federal Register notice, discusses the interpretation of *E-coli* results and indicates that "a positive control (MUG positive) culture, a negative control consisting of thermotolerant *Klebsiella pneumoniae* (MUG negative) culture and an uninoculated medium control may be necessary to interpret the results..." Standard Methods also indicates that there are limitations to using membrane filter techniques on complex matrices. These recommendations should be addressed, and the validation studies should be completed, before the States are charged with implementing the criteria by incorporating limits in NPDES permits.

**Response:**

See the preamble to today's rule, in particular section VI.C., Analytical Methods.

The commenter is incorrect in stating that EPA proposed Methods 1103 [sic], 1603, 1604, 1106 [sic] and 1600 for use in wastewater in the April 6, 2004 Federal Register. Footnote 28, found in the *E. coli* and enterococci rows, clearly states that the methods are "Recommended for enumeration of target organism in ambient water only."

EPA Methods 1103.1, 1106.1, 1600, and 1603 have been subjected to interlaboratory validation in an assortment of disinfected wastewater matrices. The validation reports will for Methods 1600 and 1603 will be issued in late 2004, and in late 2005 for Methods 1103.1 and 1106.1. In addition, these methods will be modified for use in wastewater and will include all appropriate quality control parameters, and will be available at the same time as their respective validation reports. EPA did not specifically use pulp and paper effluent matrices in the study. Method validation studies typically include several representative matrices and are not intended to include every potential effluent matrix to which a method may be applicable.

In addition, EPA's NPDES regulations do not require the existence of EPA-approved methods before establishing water quality-based effluent limitations in permits.

## Issue: Analytical Methods 5

**Organization Name:** Association of Metropolitan Sewerage Agencies

**Document ID:** 227

**Comment ID:** 284

**Comment:**

*Test Methods*

Currently there are no EPA-approved test methods for enumerating *E. coli* or enterococci in wastewater effluent. EPA has over the past few years validated and approved test methods for enumerating these indicators in ambient water, but those approvals exclude effluent as an approved sample matrix. This is a serious concern that will undermine widespread implementation of the 1986 bacteria criteria. AMSA understands that EPA is validating the approved ambient water test methods for use on effluent, but that there have been problems with false negatives during the validation efforts and that additional study may delay proposal of the methods until late 2004, with final, approved methods not available until sometime in 2005.

While many wastewater treatment agencies have begun to evaluate their effluents for the new indicators using various test methods to get out ahead of the regulations, knowledge regarding the effectiveness of current disinfection practices on enterococci and *E. coli* remains limited at best.

In preliminary studies, one AMSA member has identified differences between enterococcus methods when analyzing wastewater samples - one method (EPA Method 1600) shows consistently lower counts than the other (SM 9230C) in treated wastewater, and suggests that Method 1600 (the subject of EPA's ongoing validation efforts) is inappropriate for wastewater analysis. The marked difference between the two methods is particularly worrisome if EPA or states use enterococcus results analyzed with Method 1600 to determine achievable limits in treated wastewater. Enterococcus concentrations in chlorinated wastewater analyzed with Method 1600 may be artificially low, and these artificially low results may lead to the false conclusion that meeting proposed EPA limits is achievable in chlorinated wastewater when in fact it is not.

**Response:**

Methods 1103.1, 1106.1, 1600, and 1603 have been subjected to interlaboratory validation in an assortment of disinfected wastewaters, including wastewater disinfected by chlorination. Based on the validation study, Method 1600 was characterized with an acceptable overall mean recovery of 90.8% in disinfected wastewater. However, false negative confirmation rates in secondary and disinfected wastewaters prompted a follow-on study that indicated that 81% of atypical pink to red colonies without halos that were >0.5 mm diameter verified as enterococci. As a result, EPA recommends that pink to red colonies without halos that are >0.5 mm in diameter be verified, especially if large numbers of these colonies are observed in a particular matrix.

EPA disagrees that the lack of EPA-approved test methods for enumerating *E. coli* or enterococci in effluent will undermine implementation of these criteria in permits. EPA's NPDES regulations do not require that compliance monitoring for NPDES permits be based on EPA-approved methods.

## Issue: Analytical Methods 6

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 362

**Comment:**

False positives are also a problem for enterococci and even *E. coli* in the biologically complex liquor associated with pulp mill waste. EPA has not assessed if the problem of false positives is less for the federal criteria recommendations. We agree that effective bacterial criteria need not enumerate *Klebsiella* spp.; however, we are also not aware of any scientific validation that it is of no health significance. *Klebsiella* spp. is one of many opportunistic pathogens that may harm immune compromised individuals. Infection rates may be higher in waters with higher *Klebsiella* spp. concentrations.

**Response:**

See the preamble to today's rule, in particular section VI.C., Analytical Methods.

EPA Methods 1103.1, 1106.1, 1600, and 1603 have been subjected to interlaboratory validation in an assortment of disinfected wastewater matrices. The validation reports will for Methods 1600 and 1603 will be issued in late 2004, and in late 2005 for Methods 1103.1 and 1106.1. In addition, these methods will be modified for use in wastewater and will include all appropriate quality control parameters, and will be available at the same time as their respective validation reports. Method validation studies typically include several representative matrices and are not intended to include every potential effluent matrix to which a method may be applicable. Because the studies were for the specific organisms of the methods (i.e., *E. coli* and enterococci), the Agency did not test for *Klebsiella* species.

In EPA's epidemiological studies used as the basis for the ambient recreational water criteria, *E. coli* and enterococci exhibited the strongest positive correlation to swimming-associated gastroenteritis, the former in fresh waters only and the latter in both fresh and marine waters. The purpose of monitoring for indicators is to determine if water quality is impaired due to the presence of fecal contamination. Fecal coliforms such as *Klebsiella* are often present in pulp and paper and textile mill effluents in the absence of fecal contamination.

## **Issue: Analytical Methods 7**

Comments originally listed under this issue have been reassigned to another issue.

## **Issue: Analytical Methods 8**

**Organization Name:** Hampton Roads Sanitation District

**Document ID:** 220

**Comment ID:** 437

**Comment:**

The criterion bacteria are actually indicator organisms rather than causative agents which produce the observable or measurable response. When this data was gathered in the mid 1970's and even when this document was published (1986) the EPA had not promulgated a method for enumeration of enterococci. In fact, the EPA did not promulgate a method for the enumeration of enterococci until the early 2000's. That published method in the 2001 contained improvements to correct known problems with the methods used earlier.

**Response:**

EPA accepts this comment and thanks the commenter for their support.

## Issue: Analytical Methods 9

**Organization Name:** Association of Metropolitan Sewerage Agencies

**Document ID:** 227

**Comment ID:** 441

**Comment:**

Single sample maximum (SSM) is a seriously flawed concept for bacteria, because of the nature of bacterial sampling, detection and enumeration. Differences in single sample measurements are often meaningless. Analytical results are actually estimates of true concentrations based on a series of assumptions. This is a major reason for the established, and EPA recommended practice, of using geometric means to characterize bacterial conditions. As an example, the Most Probable Number (MPN) fecal determination is considered one of the most precise of all the bacterial density determinations. According to Standard Methods (1992), when use of the MPN technique results in a detected concentration of 110 MPN/100 ml, a 95% confidence can be used that the real number is between 40 and 300. Single sample differences between numbers like 104 (as proposed), 105 and even 150 are meaningless.

**Organization Name:** Hampton Roads Sanitation District

**Document ID:** 220

**Comment ID:** 439

**Comment:**

Single sample maximum (SSM) is a seriously flawed concept for bacteria. It is flawed because of the nature of bacterial sampling, detection and enumeration. Bacteriological sampling and measurement is as much an art as it is a science. Differences in single sample measurements are usually meaningless. Analytical results are actually estimates of true concentrations based on a series of assumptions. This is a major reason for the established, and EPA recommended practice, of using geometric means to characterize bacterial conditions. As an example, the MPN fecal determination is considered one of the most precise of all the bacterial density determinations. Further, the most precise of the MPN procedures is that using five tubes per dilution. According to Standard Methods (1992), when use of MPN technique results in a detected concentration of 110 MPN/100 ml, a 95% confidence can be used that the real number is between 40 and 300. Single sample differences between numbers like 104, 105 and even 150 are meaningless. Thus establishment of single sample maximum, such as 104 for enterococci, sets the stage for numerous negative consequences in the absence of meaningful benefits. When beaches are not closed following the measurement of a 105 or 150, numerous negative consequences could ensue. Costly court challenges could result whenever a tragic or serious illness occurs following a swimming experience and it is documented a bacterial number exceeding the criteria was detected anywhere near the affected person.

**Response:**

See the preamble to today's rule, in particular section VI.C., Analytical Methods.

Membrane filtration procedures are generally considered to be more precise than MPN procedures (see *Standard Methods 9222B.6.c, 20th edition*). For example, a concentration of 20 MPN/100 mL results has a 95% confidence interval of 6.8 to 40 MPN/100 mL. In contrast, the same confidence interval for 20 CFU/100 mL sample is 12.2 to 30.8 CFU/100 mL.

As indicated in Table 3 of today's rule, the following membrane filtration procedures may be used for the determination of *E. coli* in fresh recreational waters: Methods 1103.1, 1603, and 1604 or

equivalent. (It should be noted that the method numbers in footnote a for Tables 2 and 3 in the July 9, 2004 FR proposal for *E. coli* and enterococci, respectively, should be reversed - the method numbers for the *E. coli* test were in Table 3, footnote a.) As a result, method equivalency would have to be demonstrated prior to using another procedure, such as an MPN method. It should also be noted that Methods 1103.1 and 1603 have been subjected to interlaboratory validation in an assortment of disinfected wastewaters, including wastewater disinfected by chlorination, and final reports will be available in late 2004.



## **Issue: Analytical Methods 10**

**Organization Name:** Hampton Roads Sanitation District

**Document ID:** 220

**Comment ID:** 440

**Comment:**

It was not until 2001 that the EPA promulgated a method for determining these bacteria in ambient waters. There are still no methods identified by which the bacteria can be quantified in effluents.

**Response:**

See the preamble to today's rule, in particular section VI.C., Analytical Methods.

EPA Methods 1103.1, 1106.1, 1600, and 1603 have been subjected to interlaboratory validation in an assortment of disinfected wastewater matrices. The validation reports will for Methods 1600 and 1603 will be issued in late 2004, and in late 2005 for Methods 1103.1 and 1106.1. In addition, these methods will be modified for use in wastewater and will include all appropriate quality control parameters, and will be available at the same time as their respective validation reports. EPA did not specifically use pulp and paper effluent matrices in the study. Method validation studies typically include several representative matrices and are not intended to include every potential effluent matrix to which a method may be applicable.

## Issue: Analytical Methods 11

**Organization Name:** King County Department of Natural Resources and Parks

**Document ID:** 204

**Comment ID:** 443

**Comment:**

The variability of results for all the test methods will be the same, since the procedural steps are very similar in all the tests (FC, *E. coli*, and enterococcus). But the lower Maximum Contaminant Level for enterococcus is low enough that variation from natural causes (fluctuating river volume, turbidity from rain events, etc) may actually become a source of method interference and could cause results to exceed the standard, particularly if only monitored infrequently. Given that EPA believes the enterococcus count is correlative to disease, how does elevation of enterococcus count in pristine waters or large bodies of urban waters with no sewage impact relate effective assessment of risks? We feel this issue of natural variation, at least in the northwest, is an important example of the liabilities of such a nationwide application of enterococcus.

**Response:**

EPA recognizes that the indicators *E. coli* and enterococci are not specific to human fecal contamination. However, since animal sources may result in human illness, the use of these indicators for fecal contamination in general provides a higher level of human health protection.

## **Issue: Bacteria Criteria 1**

**Organization Name:** American Society for Microbiology

**Document ID:** 162

**Comment ID:** 39

**Comment:**

The ASM offers the following recommendations in an effort to address some of the issues found in the proposed rule.

**ISSUE:** The level of acceptable risk in the proposed rule is based on criteria used in 1986, and only for gastrointestinal illness. It is not evident that the level of risk acceptable today is the same as in 1986, nor is it evident that risk assessments should be restricted to gastrointestinal illness and ignore respiratory or other illnesses associated with fecal contamination.

**SOLUTION:** The EPA should assess the need for revising levels of acceptable risk and for including additional illnesses associated with exposure to contaminated recreational waters.

**Response:**

As part of its requirements under CWA section 304(a)(9), EPA is working on developing new criteria, and expects to publish those criteria by October 2005. Epidemiological studies currently underway to determine these criteria will capture many types of endpoints, such as respiratory, dermal, or eye, ear, nose and throat symptoms or infections, as well as gastrointestinal illness. These studies will also statistically evaluate sampling strategies, data analysis, and management techniques to determine acceptable levels of fecal contamination. These studies will also study representativeness and applicability of the bacteria criteria on a national level. Once the new criteria have been developed, EPA will collect input from a wide range of stakeholders, in the same way that comment has been solicited and incorporated into criteria historically.

Today's rule does not change the risk level because the purpose of this rulemaking is to put in place EPA's 1986 bacteria criteria for those states that have failed to do so, not to change the acceptable level of risk on which the criteria were based. EPA expects to evaluate the acceptable risk levels when EPA develops new criteria for pathogens and pathogen indicators.

## Issue: Bacteria Criteria 2

**Organization Name:** American Society for Microbiology

**Document ID:** 162

**Comment ID:** 42

**Comment:**

The ASM offers the following recommendations in an effort to address some of the issues found in the proposed rule.

**ISSUE:** The proposed rule continues to emphasize a select group of bacterial indicator species, even though the ecological behavior of these indicators is not fully known and may confound predictions of risk of illness. Other indicators, e.g., bacteriophages of *Escherichia coli* such as F+ coliphage), may prove more reliable and offer methodological advantages deriving from the use of either rapid molecular approaches and traditional but relatively rapid (e.g. 8 hours) culture-based approaches.

**SOLUTION:** The EPA should assess the reliability and utility of existing and new indicator species, including coliphages. In addition, the EPA should support detailed assessments of indicator species ecology, particularly with respect to persistence and growth in receiving waters and sediments.

**ISSUE:** The proposed rule properly emphasizes pathogens associated with waterborne disease, but provides for no specific monitoring or studies of pathogens. The probability of illnesses from waterborne pathogens depends on the type of contact, exposure time, pathogen concentrations in contaminated water, pathogen survival in receiving waters, pathogen transport from source to contact point, and the level of individual or population susceptibility to waterborne pathogens.

Due to the numerous sources of contamination now known to affect recreational waters, (especially combined sewer overflows) and factors such as seasonal variations in sewage discharge disinfection and pathogen accumulation in sediment and sands, specific studies of waterborne pathogens are essential. Such studies must focus on pathogen distribution, dynamics and association with disease.

New studies are particularly important for establishing risks from human and non-human sources of fecal contamination in recreational waters, and for determining the most appropriate strategies and funding allocations for wastewater management.

**SOLUTION:** EPA should establish a variety of adequately funded research programs, including extramural programs, to gather data on pathogen occurrence and impacts for critical recreational areas affected by combined sewage overflows and other pathogen-laden sewage discharges.

**Response:**

As part of its requirements under CWA section 304(a)(9), EPA is working on developing new criteria, and expects to publish those criteria by October 2005. Epidemiological studies currently underway to determine these criteria will capture many types of endpoints, including gastrointestinal disease. These studies will also statistically evaluate sampling strategies, data analysis, and management techniques to determine acceptable levels of fecal contamination. These studies will also study representativeness and applicability of the bacteria criteria on a national level. Once the new criteria have been developed, EPA will collect input from a wide

range of stakeholders, in the same way that comment has been solicited and incorporated into criteria historically.

### Issue: Bacteria Criteria 3

**Organization Name:** American Society for Microbiology

**Document ID:** 162

**Comment ID:** 44

**Comment:**

The ASM offers the following recommendations in an effort to address some of the issues found in the proposed rule.

**ISSUE:** The proposed rule relies on use of geometric means and single sample maxima for assessing water quality. While these statistical approaches have merit, research since 1986 has raised questions about their utility that remain unresolved. For example, the use of arithmetic means has become a more accepted practice in other areas of applied public health microbiology, such as food safety microbiology.

**SOLUTION:** The EPA should conduct thorough statistical evaluations of sampling strategies (including sampling frequency) and data analysis and management to determine the most appropriate parameter(s) for use in establishing acceptable and unacceptable levels of fecal contamination.

**Organization Name:** Association of Metropolitan Sewerage Agencies

**Document ID:** 227

**Comment ID:** 286

**Comment:**

*Concerns Regarding the SSM*

SSM is also flawed in this specific case because of the particular statistical approach used in the initial 1986 criteria. While AMSA would argue that the data were flawed, the geometric mean standards for the 1986 criteria were at least developed from actual data. The proposed SSM values were based only on statistical assumptions of log probability distribution and an arbitrarily selected "confidence limit." As stated in the original 1986 criteria relative to this confidence interval, "[t]o set the single sample maximum, it is necessary to specify the desired chance that the beach will be left open when the protection is adequate. This chance, or confidence level, was based on Agency judgment" (January 1986; page 9). Using a control chart analogy and the actual log standard deviations from the 1970 studies, SSM for various confidence levels were calculated. The result was to select the 75% confidence interval around a geometric mean. The statistical analysis was based on the assumption that this data set had a log normal distribution. Following the selection of this confidence level, EPA again cautioned that the development and listing of the SSMs for this specific data set "*should be recalculated for individual areas if significant differences in log standard deviations occur.*"

**Organization Name:** Hampton Roads Sanitation District

**Document ID:** 220

**Comment ID:** 435

**Comment:**

SSM is also flawed in this specific incidence because of the particular statistical approach used in the initial 1986 criteria. Statistically a geometric mean standard was developed from actual data. The data is flawed but at least actual data was used to arrive at this number. The proposed single

sample maximum was based only on statistical assumptions assuming log probability distribution and an arbitrarily selected "confidence limit". As stated in the original 1986 criteria relative to this confidence interval, "To set the single sample maximum, it is necessary to specify the desired chance that the beach will be left open when the protection is adequate. This chance, or confidence level, was based on Agency judgment." using a control chart analogy and the actual log standard deviations from the 1970 studies, SSM for various confidence levels were calculated. The result was to arbitrarily select the 75% confidence interval around a geometric mean. The statistical analysis was based on the assumption of this data set had a log normal distribution. Following the arbitrary selection of this confidence level, the EPA repeated its caution about the development and listing of the SSMs for this specific data set, "These SSM levels should be recalculated for individual areas if significant differences in log standard deviations occur." Most important to note is that the assumptions used to calculate the SSM are arbitrary and, perhaps even more significant, that single sample maximum of 104 was determined not by epidemiological studies but rather using statistical assumptions.

**Organization Name:** Northeast Ohio Regional Sewer District

**Document ID:** 198

**Comment ID:** 310

**Comment:**

**Derivation of SSM Values**

1) Between the document "Health Effects Criteria for Fresh Recreational Waters" (August 1984) and the 1986 Criteria Document, the term "one-sided confidence level" creeps in. This terminology does not correspond to confidence levels with which we are familiar and, in fact, represents an entirely different concept. The calculations and constants used are actually for the nth percentile based on the cumulative distribution function of the normal distribution, transformed to lognormal. In other words, the calculation described merely indicates relative positioning of values from the stated distribution. For example, 235 per 100 mL represents the value above which 25 percent of the sample population can be expected to fall. Therefore, we request that the misleading terminology in the regulation be replaced with the correct terms; i.e., "confidence level factor" should read "cumulative distribution function percentile value." The existing language is both incorrect and misleading.

2) The choice of percentiles used in developing the SSM values is arbitrary and capricious and without any scientific basis.

3) The data used in derivation of the SSM criteria was improperly pooled. The standard deviation calculations were apparently based on either all freshwater samples or all marine samples. However, it is clear that the samples taken at "Beach A" represent a different population from those taken at "Beach B" and that the same applies to "Beach E" and "Beach W." Therefore, it is clear that the calculations for SSM criteria are flawed and there is no scientific basis for them.

**Organization Name:** Northeast Ohio Regional Sewer District

**Document ID:** 198

**Comment ID:** 459

**Comment:**

**Evaluation of Various Means of Regulating Bacteria**

## INTRODUCTION

Based on field studies, U.S. EPA published *Health Effects Criteria for Fresh Recreational Waters* (August 1984), which became a part of the basis for *Ambient Water Quality Criteria for Bacteria* - 1986 (January 1986). These documents form a basis for evaluating waters to protect human health based on an acceptable incremental illness rate of 8 per thousand swimmers.

The intent of this paper is to evaluate two different approaches to evaluating bacterial contamination in fresh waters:

- The basis presented in the above documents ("U.S. EPA Criteria");
- The *E. coli* provisions of Ohio Administrative Code Section 3745-1-07 ("OAC").

This paper will examine the criteria for what are variously referred to as "Designated Beach Areas" and "Bathing Waters" for fresh water.

## GEOMETRIC MEAN

Bacterial contamination is evaluated based on geometric mean calculations. Due to the ambiguities involved in measuring it and the natural variation in bacterial densities, this has proven to be the most effective way to evaluate and regulate bacteria.

The geometric mean, despite its strengths, has a shortcoming: it will tend to "bury" short term high levels of contamination. The Federal and State approaches dealing with this weakness are vastly different.

**Organization Name:** Northeast Ohio Regional Sewer District

**Document ID:** 198

**Comment ID:** 471

### Comment:

#### Federal Approach

The U.S. EPA Criteria limit the maximum allowable single sample result at a level equal to the 75<sup>th</sup> percentile value for a lognormal distribution having the geometric mean criterion as its mean and a logarithmic standard deviation of 0.4. This results in a "Single Sample Maximum" (SSM) of 235 per 100 mL. The major shortcoming of this approach is that, while the referenced distribution by definition meets the geometric mean criterion, fully 25% of its population will lie above the SSM value.

#### State Approach

OAC takes a different approach to guarding against spikes in bacterial contamination. It includes two safeguards:

- It evaluates each thirty-day period individually, limiting the population available to "dilute" a contamination event.
- It limits the number of samples allowed to exceed the U.S. EPA Criteria SSM level to no more than 10% of the samples taken in any thirty-day period.



**Response:**

EPA notes that the epidemiological methodology, as well as the methods of analyzing the data, used in the earlier EPA studies were peer reviewed as described in section VI.A. of the preamble to today's rule, and have been widely used since, indicating their general acceptance worldwide. Statistical analysis varies widely in technique and practice. The arithmetic mean may be a more conservative measurement than the geometric mean in some cases, but as a means of measuring water quality it is not always the most effective averaging method. Use of the arithmetic mean, instead of the geometric mean is also being investigated in the current epidemiological studies.

EPA recognizes the limitations of using a geometric mean of bacterial densities as the basis for protecting public health. The bacterial density that a person is actually exposed to is what leads to illness. However, the 1986 bacteria criteria were developed based on relating illness in people who were immersed in water to the geometric mean bacteria densities at the beach. Clean Water Act section 303(i) requires EPA to promulgate these criteria for States and Territories that have not adopted water quality standards as protective of human health as EPA's 1986 bacteria criteria. EPA understands the limitations of using the geometric mean and is considering this as EPA develops new criteria for pathogens and pathogen indicators.

EPA also recognizes the limitations of the single sample maximums as described in the 1986 bacteria criteria document. However, as described in the paragraph above, the Clean Water Act requires EPA to promulgate these criteria. EPA understands the limitations of using the single sample maximums and is considering this as EPA develops new criteria for pathogens and pathogen indicators.

## Issue: Bacteria Criteria 4

**Organization Name:** Association of Metropolitan Sewerage Agencies

**Document ID:** 227

**Comment ID:** 282

**Comment:**

AMSA's comments on the proposed rule follow for your consideration.

*Continuing Concerns with the 1986 Criteria*

AMSA continues to question the scientific validity of the 1986 Ambient Water quality Criteria for Bacteria.<sup>2</sup> On a number of occasions, AMSA has commented on the flaws in the original studies underlying the criteria and the fact that no studies to confirm the criteria have been conducted since they were first established.

*A. Underlying Studies and Data Have Not Been Validated*

The 1986 enterococci criterion, for example, was developed based on very limited and known to be highly polluted U.S. coastal marine environments. The sampling only looked at New York City, NY; Lake Ponchartrain, LA; and Boston Harbor, MA beaches. These data were further limited to narrow testing periods: 1973 to 1975 for New York City; 1977 and 1978 for Lake Ponchartrain; and 1978 for Boston Harbor. We are not aware of any recent examination of beaches noted for uncontaminated, pristine swimming conditions, nor of published literature post-1980 that verifies the 1986 criteria values.

*B. Study Results Inconclusive and Potentially Biased*

A closer look at the studies used to support the 1986 criteria reveals additional problems. Nine testing periods were used for data collection and statistical comparison of the results at New York City beaches, but only two (22%) of the nine tests found a statistically significant difference in the illness symptoms between swimmers and non-swimmers. In addition, the determination of illness in all the studies came from highly-subjective-and often erroneous-self-diagnosis of interviewed persons. These persons often were members of the same family unit, creating additional potential bias in the reported illnesses.

*C. Criteria Fail to Consider Non-Human Sources of Contamination*

The 1986 criteria also look only at human bacterial contributions. However, it is now possible to routinely and economically determine the source of fecal indicator organisms, whether stemming from humans, birds, pets, livestock, or wildlife. Recent studies in Virginia, for example, in areas with elevated enterococci levels have shown that natural sources of bacteria, such as geese, seagulls and wildlife, can significantly impact bacterial counts. EPA has not provided guidance on how to account for the impact of these sources on bacterial counts when implementing the 1986 criteria.

*D. Additional Research Is Needed Before Criteria Are Implemented*

Our knowledge of bacterial sources and contamination has advanced significantly since the data underlying the criteria were collected in the 1970's and the criteria were published in 1986. The methods of enumeration have also improved to eliminate old problems that had unknown effects

on the analysis results. Ultimately, the only way to respond to these serious concerns regarding the 1986 criteria is for EPA to conduct additional research using up-to-date methods and experience on the suitability of *E. coli* and enterococci as indicator organisms. Given that the statutory deadlines in the BEACH Act will not allow EPA to take additional research and epidemiological studies into consideration before states are required to make wholesale changes to their water quality standards and discharge permits, AMSA urges EPA to work with the states and permittees to implement the new standards in as careful and responsible a manner as is possible.

**Footnote:**

<sup>2</sup> *Ambient Water Quality Criteria for Bacteria*, January 1986, EPA 440/5-84-002

**Response:**

EPA's epidemiological studies found only a low correlation between fecal coliform and swimming-related illness. Enterococci and *E. coli* were demonstrated to be the best indicators related to swimming-associated illness. Epidemiological studies performed since 1986 have substantiated the results of EPA's studies by exhibiting the same relationship between *E. coli* or enterococci and illness rates. In other words, as the amount of the indicator in the waters increased, the number of illnesses increased as well. This relationship was independent of the geographical location of the studies and the population studied.

As part of its requirements under CWA section 304(a)(9), EPA is working on developing new criteria, and expects to publish those criteria by October 2005. Epidemiological studies currently underway to determine these criteria will capture many types of endpoints, such as respiratory, dermal, or eye, ear, nose and throat symptoms or infections, as well as gastrointestinal illness. These studies will also statistically evaluate sampling strategies, data analysis, and management techniques to determine acceptable levels of fecal contamination. These studies will also study representativeness and applicability of the bacteria criteria on a national level. Once the new criteria have been developed, EPA will collect input from a wide range of stakeholders, in the same way that comment has been solicited and incorporated into criteria historically.

Studies of non-human sources are outlined in EPA's current epidemiological study plan. EPA agrees that more research in this area is warranted, and EPA is currently supporting efforts to determine sources of contamination. However, EPA would like to remind the commenters that microbial source tracking is a developing science and particular source tracking techniques have not been validated nationally.

## Issue: Bacteria Criteria 5

**Organization Name:** Hampton Roads Sanitation District

**Document ID:** 220

**Comment ID:** 230

**Comment:**

The sites used in the studies to develop the 1986 were non-randomly distributed and selected because of known bacterial problems from human sources, i.e. CSOs. Only three (3) sites were used to conduct all the studies for development of the saltwater criteria: Boston MA, New York NY and Lake Pontchartrain LA. Each location is unique and none can be considered representative of the hundreds of beaches in the United States where CSOs are not present. Additionally, there were no control sites or beaches used. There were no sites with natural sources of bacteria. There were clean sites without known point sources of bacterial pollution. No published literature, since these 1970 studies, verify the relationships established or confirm the criteria values.

The endpoint (gastrointestinal illness (GI)) used to establish the criteria is highly subjective and, in the vast majority of instances, self diagnosed. This endpoint lacks the basic necessities required for use as a credible endpoint for any scientific investigation. There is no way to determine such elementary characteristics as bias, precision or accuracy.

**Response:**

Enterococci and *E. coli* are not pathogens; rather, they are indicators of fecal contamination. EPA recognizes that the 1986 bacteria criteria, like all criteria based on indicators, are not perfect. Monitoring for a particular pathogen is specific to that pathogen, and not to any other related pathogens. Criteria for one pathogen is predictive of illnesses resulting only from that particular pathogen.

Sites of the epidemiological studies were chosen based on the combination of levels of fecal contamination and bather populations. Pristine waters cannot be studied, because there would be no potential exposure to pathogens and thus no measurable health endpoint.

None of the study sites were located in the Pacific Northwest or in tropical areas. While commenters make a variety of points about the uniqueness of these areas, EPA has received no information confirming that they are so different that the criteria should not be applied in those areas. Sites studied in the Great Lakes exhibit temperature profiles similar to those in Washington or Oregon. While no sites were in tropical areas, EPA is investigating the possibility of conducting future studies in a variety of temperature and geographical regimes.

EPA disagrees that gastrointestinal illness is an incorrect and imprecise endpoint. In part, this endpoint was used because it reflects an endpoint associated with the fecal-oral route of transmission, which can be mitigated through source controls. Additionally, other endpoints were evaluated during the studies, but no correlation between those endpoints and water quality was observed.

## **Issue: Bacteria Criteria 6**

**Organization Name:** Hampton Roads Sanitation District

**Document ID:** 220

**Comment ID:** 232

**Comment:**

The 1986 work was a preliminary first step toward the development of a criteria. However the EPA failed to take any additional steps. There is no published data to verify that relationship between confirmed instances of GI illness and exposure to the recommended criteria levels of enterococci. It has never been verified that GI impact is even the correct endpoint on which to base determination of effect. The chosen endpoint (GI illness) to determine the effect of bacterial contamination, as currently used, lacks the characteristics needed for valid statistical comparisons.

**Response:**

EPA's epidemiological studies found only a low correlation between fecal coliform and swimming-related illness. Enterococci and *E. coli* were demonstrated to be the best indicators related to swimming-associated illness. Epidemiological studies performed since 1986 have substantiated the results of EPA's studies by exhibiting the same relationship between *E. coli* or enterococci and illness rates. In other words, as the amount of the indicator in the waters increased, the number of illnesses increased as well. This relationship was independent of the geographical location of the studies and the population studied.

EPA disagrees with the claim that gastrointestinal illness is an incorrect and imprecise endpoint. In part, this endpoint was used because it reflects an endpoint associated with the fecal-oral route of transmission, which can be mitigated through source controls. Additionally, other endpoints were evaluated during the studies, but no correlation between those endpoints and water quality was observed.

Enterococci and *E. coli* are not pathogens; rather, they are indicators of fecal contamination. EPA recognizes that the 1986 bacteria criteria, like all criteria based on indicators, are not perfect. Monitoring for a particular pathogen is specific to that pathogen, and not to any other related pathogens. Criteria for one pathogen is predictive of illnesses resulting only from that particular pathogen.

## Issue: Bacteria Criteria 7

**Organization Name:** Hampton Roads Sanitation District

**Document ID:** 220

**Comment ID:** 438

**Comment:**

Peer reviewed scientific literature studies suggested methods, used in the original studies by which the 1986 criteria were set, likely underestimated the bacterial densities of the tested waters. These investigations (Rhodes and Kator 1996; Pagel and Hardy 1980; Dutka and Kwan 1978) reported under estimations of measured bacterial densities up to 73% using the same methods as used to develop the criteria. False positives were not the problem but false negatives were frequent. This means the measured bacterial densities likely underestimated the actual concentrations. Therefore the criteria based on them would be too conservative. The EPA's own cited supporting studies also implied the original data may have been incorrect. Overseas investigations including Cheung et al. (1990), Fattal et al. (1987), Von Schirnding et al. (1992) and McBride (1998) consistently measured much higher enterococci levels than reported in the original EPA studies. Negative health effects were not determined at the EPA criteria concentrations.

**Response:**

EPA's epidemiological studies found only a low correlation between fecal coliform and swimming-related illness. Enterococci and *E. coli* were demonstrated to be the best indicators related to swimming-associated illness. Epidemiological studies performed since 1986 have substantiated the results of EPA's studies by exhibiting the same relationship between *E. coli* or enterococci and illness rates. In other words, as the amount of the indicator in the waters increased, the number of illnesses increased as well. This relationship was independent of the geographical location of the studies and the population studied.

EPA notes that the epidemiological methodology, as well as the methods of analyzing the data, used in the earlier EPA studies were peer reviewed as described in section VI.A. of the preamble to today's rule, and have been widely used since, indicating their general acceptance worldwide.

## Issue: Bacteria Criteria 8

**Organization Name:** King County Department of Natural Resources and Parks

**Document ID:** 204

**Comment ID:** 332

**Comment:**

Moving to enterococcus for all coastal waters implies that this standard is the best, most well studied indicator for all waters - those receiving direct discharges and those receiving only indirect discharges of pollutants. However the epidemiological studies cited in EPA's 1986 criteria documentation looked at data on a variety of indicators (*E. coli*, enterococcus, *Staphylococcus*, *Pseudomonas*, *Clostridium perfringens*) but all were performed in recreational waters impacted directly by wastewater treatment facilities. While these study's objectives were to find indicators which best correlation to incidence of human disease, none appear to have as their objective, evaluating the best indicators of all bacterial sources including nonwastewater sources such as wildlife or domestic animals. The efficacy of enterococci as indicators on waterbodies with little or no direct wastewater discharge has not been well studied nor has the association of pathogen presence been documented.

**Response:**

EPA's epidemiological studies found only a low correlation between fecal coliform and swimming-related illness. Enterococci and *E. coli* were demonstrated to be the best indicators related to swimming-associated illness. Epidemiological studies performed since 1986 have substantiated the results of EPA's studies by exhibiting the same relationship between *E. coli* or enterococci and illness rates. In other words, as the amount of the indicator in the waters increased, the number of illnesses increased as well. This relationship was independent of the geographical location of the studies and the population studied.

Sites of the epidemiological studies were chosen based on the combination of levels of fecal contamination and bather populations.

As part of its requirements under CWA section 304(a)(9), EPA is working on developing new criteria. Epidemiological studies currently underway to determine these criteria will capture many types of endpoints, such as respiratory, dermal, or eye, ear, nose and throat symptoms or infections, as well as gastrointestinal illness. These studies will also statistically evaluate sampling strategies, data analysis, and management techniques to determine acceptable levels of fecal contamination. These studies will also study representativeness and applicability of the bacteria criteria on a national level. Once the new criteria have been developed, EPA will collect input from a wide range of stakeholders, in the same way that comment has been solicited and incorporated into criteria historically.

Studies of non-human sources are outlined in EPA's current epidemiological study plan. EPA agrees that more research in this area is warranted, and EPA is currently supporting efforts to determine sources of contamination. However, EPA would like to remind the commenters that microbial source tracking is a developing science and particular source tracking techniques have not been validated nationally.

## **Issue: Bacteria Criteria 9**

**Organization Name:** Northeast Ohio Regional Sewer District

**Document ID:** 198

**Comment ID:** 460

### **Comment:**

#### **Beach Research Implications**

The proposed rulemaking does not allow the necessary flexibility to design tailored programs to maximize the protection of public safety in certain situations. Study findings from a particular major beach in the Greater Cleveland area are leading to the conclusion that beach sands and the ground water below beach sand can be a source of bacteria that can be released during the presence of the particular high wave conditions that are experienced by this beach. While source-tracking studies are not complete, it is most likely that shorebirds are the primary source of this contamination. Work is currently underway to develop predictive modeling that would alert the public to these periods of increased risk of high bacteria densities. Based upon a variety of environmental conditions including sophisticated measures of wave energy and reach onto beach sands, we are hopeful of developing strong predictive models applicable to dry or low-rain situations. Our preliminary studies indicate that, after high waves have settled for 24 hours, beach waters are likely to exhibit bacteria densities well within standards. We believe the above-described predictive alert system could be of significant value in assisting with beach management for the protection of human health.

From our years of involvement with research at this beach, it is also obvious to us that such a model cannot be maintained at a reliable state without a sufficient ongoing supply of data. We sample this particular beach five times per week; however, our studies are showing that additional sampling is necessary to characterize the bacteria levels associated with these wave events which, in a period of four-to-six hours, can dramatically change water quality bacteria levels. Further, we suspect that changing conditions at the beach, particularly changes in the contours of the sand, will require ongoing correlation studies to keep the predictive model in optimum condition. All of this suggests the need for selective sampling during dry-weather wave conditions that produce high bacteria densities. Under all of the proposed rule options, the proposed selective sampling of our proposed beach management efforts would result in erroneous conclusions regarding water quality. To maintain high reliability for the predictive model, we explicitly expect to be sampling at the precise times when bacteria concentrations are at maximum levels. We strongly discourage the Agency from adopting any rule that uses a Single Sample Maximum as the basis for finding that a beach is in violation of water quality standards. Such a rule would penalize and discourage the very objective of protection of public health that is the driving force behind the standard. Additionally, we note that a selective sample chosen to characterize infrequent conditions could not be statistically valid for use in characterizing risk under the statistical methods described in the 1986 water quality criteria.

It is also obvious that intensive sampling around events that produce high bacteria densities will also cause the geometric mean of the data set for this beach to be erroneously elevated. Again, selective sampling to characterize infrequent events would lead to an erroneous characterization of the standard conditions at the beach. To avoid this problem, we recommend creation of a provision that allows for the nullification of selective sampling to characterize high bacteria events. For example, for standard reporting to water quality management agencies, a beach manager might only report those samples taken during the regular daily sampling time.



**Organization Name:** State of Hawaii Department of Health/Environmental Health Administration

**Document ID:** 195

**Comment ID:** 393

**Comment:**

**Reliability of Indicators**

For tropical waters there are questions about the reliability of enterococcus as a bacterial indicator for rule-making and decision-making for control of public health risks associated with fecal contamination in coastal recreational waters.

Some scientists, including a leading Hawaii water researcher, believe that research demonstrates that fecal indicators in damp soil and in water originate primarily from nonhuman sources and both survive and multiply in soil and sediment reservoirs. Human sources identifiable as a result of sewage spills are immediately controlled, even before sampling results are available, but other sources are very difficult to track back to sources in Hawaii's watersheds.

Differing views among the experts result in our having a low degree of confidence in the validity of EPA's indicator bacteria criteria, especially where most pollution sources are non-point in origin. We refer to Fujioka & Byappanahalli.<sup>1</sup> We are concerned about false positives and their implications.

On this subject we attach our response to public hearings testimony regarding proposed amendments to DOH Hawaii Administrative Rules (HAR), Chapter 11-54, Water Quality Standards.

**Footnote:**

<sup>1</sup> Fujioka & Byappanahalli. 2003. Proceedings and Report: Tropical Water Quality Indicator Workshop, Special Report SR-2004-01, University of Hawaii at Manoa, Water Resources Research Center, Honolulu, HI.

**Response:**

Sites of the epidemiological studies were chosen based on the combination of levels of fecal contamination and bather populations. Pristine waters cannot be studied, because there would be no potential exposure to pathogens and thus no measurable health endpoint. Commenters are correct that studies did not take rain days into account when developing the correlation between the indicators and illness rate. However, this was a consequence of the fact that there were no swimmers at beaches on rainy days, not because of the studies' design.

None of the study sites were located in the Pacific Northwest or in tropical areas. While commenters make a variety of points about the uniqueness of these areas, EPA has received no information confirming that they are so different that the criteria should not be applied in those areas. Sites studied in the Great Lakes exhibit temperature profiles similar to those in Washington or Oregon. While no sites were in tropical areas, EPA is investigating the possibility of conducting future studies in a variety of temperature and geographical regimes.

EPA recognizes that there are differing views among experts about appropriate microbial indicators in tropical waters. EPA agrees that this was one of the main topics examined by the experts in the cited Tropical Water Quality Indicator Workshop.

During the workshop, the experts explicitly discussed the issue of "alternate indicators". The experts declined to endorse *C perfringens* or other indicators as an alternate (i.e., substitute) indicator because there was no obvious alternative that worked better. Part of their general reasoning was the absence of health risk data for other indicators. Another part was conflicting information from the various studies.

Instead they recommended the continued use of the current EPA-recommended indicators, despite the complications discussed in the presentations. They recommended supplementing the current indicators with other indicators. This group consensus was explicitly incorporated into the Consensus Statements #4 and #4-alternate.

Today's rule does not establish monitoring requirements for beach monitoring and notification programs, or for any other Clean Water Act application. States may develop monitoring regimes to suit their particular needs. EPA agrees that site specific modeling of beaches can be a helpful beach management tool. EPA is currently looking into the application of beach models that forecast the water quality of beach waters.

Studies on re-growth of indicators in tropical waters or in beach sand have also been inconclusive. Recent studies have all studied the amount of indicators in the beach sand; there has not been any research into the amount of pathogens in the sand, and the health risk resulting from those pathogens. This is also an area of research that EPA is planning to pursue in the future.

## **Issue: Bacteria Criteria 10**

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 344

**Comment:**

The bather studies should not be relied upon to make risk-based decisions.

**Response:**

Sites of the epidemiological studies were chosen based on the combination of levels of fecal contamination and bather populations. Pristine waters cannot be studied, because there would be no potential exposure to pathogens and thus no measurable health endpoint.

EPA's epidemiological studies found only a low correlation between fecal coliform and swimming-related illness. Enterococci and *E. coli* were demonstrated to be the best indicators related to swimming-associated illness. Epidemiological studies performed since 1986 have substantiated the results of EPA's studies by exhibiting the same relationship between *E. coli* or enterococci and illness rates. In other words, as the amount of the indicator in the waters increased, the number of illnesses increased as well. This relationship was independent of the geographical location of the studies and the population studied.

Enterococci and *E. coli* are not pathogens; rather, they are indicators of fecal contamination. EPA recognizes that the 1986 bacteria criteria, like all criteria based on indicators, are not perfect. Monitoring for a particular pathogen is specific to that pathogen, and not to any other related pathogens. Criteria for one pathogen is predictive of illnesses resulting only from that particular pathogen.

## Issue: Bacteria Criteria 11

**Organization Name:** Hampton Roads Sanitation District

**Document ID:** 220

**Comment ID:** 229

**Comment:**

Our analyses of the information provided in support of the 1986 bacterial criteria including SSMs demonstrates that there is a fundamental and overriding problem with that criteria. The current established criteria values are flawed. This is one of most compelling reasons that those criteria published in 1986 have not been implemented in many states, eighteen (18) years later, in 2004. The bacterial data and subsequent relationship to incidence of gastrointestinal illness on which the criteria were developed are parochial in distribution, and, unconvincing in substance and nature. The EPA erred when they chose not to follow up on some good initial studies which indicated, in a few of the conducted studies, that a correlation was present between levels of enterococci bacteria and the incidence of gastrointestinal illness.

The EPA has established a water quality criteria for the bacteria, *E. coli* and enterococci but comments herein are directed only to enterococci. These criteria were based on a document published in 1986 (EPA 1986) which used data from the late 1970's to base the conclusion that enumeration of enterococci was an effective method of protecting saltwater bathers from gastrointestinal illness.

The criterion bacteria are actually indicator organisms rather than causative agents which produce the observable or measurable response.

**Organization Name:** William Hastback

**Document ID:** 157

**Comment ID:** 274

**Comment:**

It is my strong belief that EPA's guidelines for bathing beach (enterococcus) standards for marine waters are not adequately supported by the "studies" they cited in support of the standards.

In regard to the "studies" EPA cites from 1983 or 1984 that resulted in the proposed enterococcus standards for marine water bathing beaches, they are a joke. Those studies relied on anecdotal information, not hard clinical data, reported to them by beach goers who were contacted 10 days after they either swam or visited the beach but did not swim. No clinical information exists as to what pathogens may have caused the illnesses reported in those studies. How was it determined that the pathogens that caused the reported illnesses had any relation to enterococcus or bathing? Were food histories for the ill subjects collected to rule out foodborne illnesses that may have been contracted in association with beach visits, such as consuming food available at public concessions at the beach?

What is at least as troubling as EPA proposing new bathing beach indicator organisms based solely on anecdotal information and not hard clinical data is the fact that in the intervening 18 years since those so-called studies were conducted, EPA has not seen fit to perform any additional studies. EPA pathetically refers to nine (9) additional studies illnesses in marine bathing beach users for support of the enterococcus standards they proposed in 1986. Of those 9 studies, only one (1) was conducted in marine waters in the U.S.

What is the basis for assuming that the pathogens in foreign bathing beach waters are the same as those that might be present in marine bathing areas in the U.S.? The sanitary systems in some of the countries included in those studies 20 years ago were not equivalent to those in the U.S. then or now. The populations that utilize the beaches in those countries are exposed to different pathogens due to the nature of the sanitation systems, local land use, food production/preparation methods and general health of the populations. The pathogens being shed into the environment by populations in those countries are different and that creates a difference in the risk associated with bathing at beaches contaminated by those different pathogens.

A review of the bathing beach studies that EPA cited in the review draft as support for their proposed enterococcus standards for marine bathing beaches reveals that of those 9 studies, four (4) did not even analyze for enterococcus in the bathing areas. How can any conclusions supporting an enterococcus standard over a fecal coliform standard be drawn from those four studies? They should be thrown out.

Of the remaining five (5) only two (2), Fattal et al 1987 in Israel and McBride et al in New Zealand reported enterococci as being more predictive of illness. And both those studies relied on anecdotal information from those reportedly ill. No clinical confirmation of illness or identification of the cause of illness was provided.

In 1990, Chung et al, reported the best relation between reported illness and w/q indicators was with *E. coli*, not enterococcus!

In 1991, Balarajan et al, did not report the methods used to evaluate water quality in the bathing area! Throw it out, why was it even mentioned?

The Von Schirring study of two bathing beaches in South Africa concluded that rates of gastrointestinal illness were higher in bathers at the more polluted beach, but the differences were not statistically significant. Again, why does this support using enterococcus over fecal coliforms?

**Organization Name:** William Hastback

**Document ID:** 157

**Comment ID:** 275

**Comment:**

The most recent study and the ONLY one conducted in the U.S. showed some positive association between anecdotally reported G-I illness and enterococci. However, the study reports that the TC vs. FC ratio was the most informative, with diarrhea and credible reports of G-I illness linked to the lower TC vs. FC ratio regardless of the absolute level of FC. Enterococcus was not a better indicator in that study.

Based on these weak studies, which rely almost exclusively on anecdotal information from subjects, there is no reason to believe that an indicator in Asia or Africa is a suitable indicator in North America. Only controlled studies in which ill and non-ill participants provide blood and/or stool samples would be rigorous enough to provide highly reliable information on the association of the presence of indicator organisms in marine bathing waters and rates of post-exposure illness.

Additionally, the appalling lack of clinical data from blood or stool samples make it such that these studies were unable to determine if those individuals that reported illness were made ill by naturally occurring marine bacteria that have no association with fecal contamination of marine

bathing waters and/or sewage discharges. Certain natural marine species of *Vibrio* bacteria (*V. cholera*, non-01 and *V. parahaemolyticus*) can make people sick with gastrointestinal symptoms that cannot be differentiated from those caused bacteria and viruses introduced to the marine environment through sewage discharge points or by human carriers shedding directly into the marine environment.

The "studies" that EPA cited as support for the enterococcus standards for marine bathing waters are all flawed because they can't rule out the possibility that some or all of the sick individuals self-reporting in the studies were made ill from bacteria that have nothing to do with fecal contamination.

Of the nine (9) studies cited ONLY one relied on actual clinical samples from subjects and it made no determination about enterococcus vs. fecal coliform levels as predictive indicators.

How can EPA realistically propose to change the bathing beach indicators on studies that are either more than 20 years old, were not conducted in the U.S. where the indicators will be used and where the majority of the studies either didn't conclude that enterococcus was a better indicator than fecal coliforms or didn't even have enterococcus water quality data?! It's absurd.

It becomes even more apparent that the adoption of the enterococcus indicator for marine bathing beach monitoring is imprudent at this time if you read page section 1.6 "Is EPA planning on conducting additional epidemiological studies in the future?" on page 11 of the draft review.

Is this short section EPA contradicts itself about three times. It states that "...EPA is conducting additional epidemiological studies that may be used to revise and develop new water quality criteria for pathogens and pathogen indicators..." it subsequently goes on to say "Future epidemiological studies and evaluation of new indicators and methods may provide new information..." and then "EPA plans to conduct epidemiological studies to support the development of new water quality indicators and associated water quality criteria guidelines for recreational waters."

**Response:**

EPA's epidemiological studies found only a low correlation between fecal coliform and swimming-related illness. Enterococci and *E. coli* were demonstrated to be the best indicators related to swimming-associated illness. Epidemiological studies performed since 1986 have substantiated the results of EPA's studies by exhibiting the same relationship between *E. coli* or enterococci and illness rates. In other words, as the amount of the indicator in the waters increased, the number of illnesses increased as well. This relationship was independent of the geographical location of the studies and the population studied.

Enterococci and *E. coli*, like fecal coliform, are not pathogens; rather, they are indicators of fecal contamination. EPA recognizes that the 1986 bacteria criteria, like all criteria based on indicators, are not perfect. Monitoring for a particular pathogen is specific to that pathogen, and not to any other related pathogens. Criteria for one pathogen is predictive of illnesses resulting only from that particular pathogen.

EPA notes that the epidemiological methodology, as well as the methods of analyzing the data, used in the earlier EPA studies were peer reviewed as described in section VI.A. of the preamble to today's rule, and have been widely used since, indicating their general acceptance worldwide. Statistical analysis varies widely in technique and practice. The arithmetic mean may be a more conservative measurement than the geometric mean in some cases, but as a means of measuring

water quality it is not always the most effective averaging method. Use of the arithmetic mean, instead of the geometric mean is also being investigated in the current epidemiological studies.

EPA disagrees with the claim that gastrointestinal illness is an incorrect and imprecise endpoint. In part, this endpoint was used because it reflects an endpoint associated with the fecal-oral route of transmission, which can be mitigated through source controls. Additionally, other endpoints were evaluated during the studies, but no correlation between those endpoints and water quality was observed.

As part of its requirements under CWA section 304(a)(9), EPA is working on developing new criteria. Epidemiological studies currently underway to determine these criteria will capture many types of endpoints, such as respiratory, dermal, or eye, ear, nose and throat symptoms or infections, as well as gastrointestinal illness. These studies will also statistically evaluate sampling strategies, data analysis, and management techniques to determine acceptable levels of fecal contamination. These studies will also study representativeness and applicability of the bacteria criteria on a national level. Once the new criteria have been developed, EPA will collect input from a wide range of stakeholders, in the same way that comment has been solicited and incorporated into criteria historically.

Studies of non-human sources are outlined in EPA's current epidemiological study plan. EPA agrees that more research in this area is warranted, and EPA is currently supporting efforts to determine sources of contamination. However, EPA would like to remind the commenters that microbial source tracking is a developing science and particular source tracking techniques have not been validated nationally.

## Issue: Bacteria Criteria 12

**Organization Name:** Massachusetts Water Resources Authority

**Document ID:** 245

**Comment ID:** 173

**Comment:**

While MWRA does not take issue with the basic components of EPA's proposal to establish national water quality criteria for bacteria in coastal waters, it is concerned that the underlying epidemiological and environmental data used to develop these recommendations is inadequate. As a consequence, the proposed guidelines may be incorporated inappropriately into NPDES permits or be applied inappropriately to receiving water standards.

**Organization Name:** NRDC, Clean Water Project

**Document ID:** 192

**Comment ID:** 208

**Comment:**

We raise a number of related issues concerning BEACH Act implementation below:

### Improved Pathogen Criteria

It is increasingly clear that EPA's recommended *E-coli* and enterococci criteria, while superior to the indicators such as fecal coliform bacteria, only correlate to the likelihood of the presence of pathogenic bacteria, and do not correlate well with the existence of other pathogen forms such as viruses. See Mark Dorfman & Nancy Stoner, *Testing the Waters*, Chapter 2, Aug. 2004, [www.nrdc.org](http://www.nrdc.org).

EPA is under a mandatory duty to develop modified coastal water quality criteria. 33 U.S.C. at 1314(a)(9). A viral indicator should be adopted as part of that requirement. EPA should proceed as quickly as possible with the development and adoption of a criterion for pathogen indicators that correlate with contamination of recreational waters by viruses and other non-bacterial pathogens. EPA should proceed with research and development of such additional water quality criterion under CWA Section 304(a)(9). EPA must revise its coastal water quality criteria by October 10, 2005. Such a 304(a)(9) criterion, once developed, should be used to review state water quality standards under Section 303(c) and to promulgate federal water quality criteria as appropriate.

**Response:**

EPA's epidemiological studies found only a low correlation between fecal coliform and swimming-related illness. Enterococci and *E. coli* were demonstrated to be the best indicators related to swimming-associated illness. Epidemiological studies performed since 1986 have substantiated the results of EPA's studies by exhibiting the same relationship between *E. coli* or enterococci and illness rates. In other words, as the amount of the indicator in the waters increased, the number of illnesses increased as well. This relationship was independent of the geographical location of the studies and the population studied.

As part of its requirements under CWA section 304(a)(9), EPA is working on developing new criteria, and expects to publish those criteria by October 2005. Epidemiological studies currently underway to determine these criteria will capture many types of endpoints, such as respiratory, dermal, or eye, ear, nose and throat symptoms or infections, as well as gastrointestinal illness.



These studies will also statistically evaluate sampling strategies, data analysis, and management techniques to determine acceptable levels of fecal contamination. These studies will also study representativeness and applicability of the bacteria criteria on a national level. Once the new criteria have been developed, EPA will collect input from a wide range of stakeholders, in the same way that comment has been solicited and incorporated into criteria historically.

## **Issue: Bacteria Criteria 13**

**Organization Name:** North Carolina Dept. of Environment and Natural Resources

**Document ID:** 190

**Comment ID:** 466

### **Comment:**

#### **Wet Weather Events**

The proposed rule, like the 1986 criteria, does not adequately address heavy rainfall, or wet weather events. From page 8 of the 1986 document, "in general, samples should be collected during dry weather periods to establish so-called "steady state" conditions. Special studies may be necessary to evaluate the effects of wet weather conditions on waters of interest especially if sanitary surveys indicate the area may be subject to storm water effects." The proposed regulation goes to some lengths to differentiate intensities of use at bathing beaches (Section III, B, 2), but fails to address the same level of clarification of the water quality standard applicability in times of "heavy rainfall." Implementation of the proposed water quality standards must adequately address these conditions to avoid improperly listing waters due to wet weather extremes beyond the management control efforts afforded to the state.

### **Response:**

The commenter is correct that the original EPA studies did not take rain days into account when developing the correlation between the indicators and illness rate. However, this was a consequence of the fact that there were no swimmers at beaches on rainy days, not because of the studies' design. EPA observed a strong relationship between enterococci levels and illness rates during the marine epidemiological studies; therefore, as enterococci levels rise the illness rate would also be expected to rise. EPA has not received any information indicating that the correlation between enterococci and illness rates is different during extreme wet weather events.

EPA intends to continue work on finalizing the Implementation Guidance to address those issues not contained in today's rule.

## Issue: Bacteria Criteria 14

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 354

**Comment:**

Bacterial criteria need to be validated in the western U.S. prior to a federal rule.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 364

**Comment:**

**III. B. Table 2:** Washington believes the EPA criteria need to be reaffirmed for waters of the west coast. There are substantial differences between the recreational waters of the west and east coasts and there is no reason to believe that the studies done on the eastern seaboard accurately represent waters on the west coast. Physical and biological differences that are not well understood may have a significant impact on the risks of illness and resulting criteria. For example, in our fresh waters fecal coliform is consistently comprised almost entirely of *E. coli*. Were this one-to-one relationship between these two indicators present in the EPA sponsored studies, a very different outcome would have occurred then to suggest fecal coliform has no relationship to illness rates fresh waters. We can only speculate on how our unique flora and colder waters influences the potential transmission rates and selection of indicators in marine waters.

**Response:**

Sites of the epidemiological studies were chosen based on the combination of levels of fecal contamination and bather populations. None of the study sites were located in the Pacific Northwest or in tropical areas. While commenters make a variety of points about the uniqueness of these areas, they did not provide any information to support their contention that their waters are so different that the criteria should not be applied in those areas. Sites studied in the Great Lakes exhibit temperature profiles similar to those in Washington or Oregon. In addition, today's rule only applies to coastal recreation waters, which are defined in 40 CFR 131.41(b)(1) as Great Lakes and marine coastal waters (including coastal estuaries) that are designated under section 303(c) of the Clean Water Act for use for swimming, bathing, surfing, or similar water contact activities. Coastal recreation waters do not include inland waters or waters upstream from the mouth of a river or stream having an unimpaired natural connection with the open sea. The comment about the relationship between fecal coliform and *E. coli* in Washington's fresh waters is outside the scope of today's rule.

## Issue: Bacteria Criteria 15

**Organization Name:** South Carolina Department of Health and Environmental Control Bureau of Water

**Document ID:** 161

**Comment ID:** 217

**Comment:**

**Issue:** The scientific validity of the 1986 criteria document and the overall effectiveness and benefits of its adoption.

The EPA has yet to address the continued and substantial state concerns regarding the scientific validity of the criteria. The criteria are now nearly 20 years old and the epidemiological data upon which they are based are even older. Moreover, there have been no studies in the intervening years to validate the selected criteria. We are particularly troubled by the fact that the previous epidemiological studies were done in areas with only one source of bacterial contamination.

**Response:**

EPA notes that the epidemiological methodology, as well as the methods of analyzing the data, used in the earlier EPA studies were peer reviewed as described in section VI.A. of the preamble to today's rule, and have been widely used since, indicating their general acceptance worldwide.

EPA's epidemiological studies found only a low correlation between fecal coliform and swimming-related illness. Enterococci and *E. coli* were demonstrated to be the best indicators related to swimming-associated illness. Epidemiological studies performed since 1986 have substantiated the results of EPA's studies by exhibiting the same relationship between *E. coli* or enterococci and illness rates. In other words, as the amount of the indicator in the waters increased, the number of illnesses increased as well. This relationship was independent of the geographical location of the studies and the population studied.

Sites of the epidemiological studies were chosen based on the combination of levels of fecal contamination and bather populations. Pristine waters cannot be studied, because there would be no potential exposure to pathogens and thus no measurable health endpoint. Commenters are correct that studies did not take rain days into account when developing the correlation between the indicators and illness rate. However, this was a consequence of the fact that there were no swimmers at beaches on rainy days, not because of the studies' design.

None of the study sites were located in the Pacific Northwest or in tropical areas. While commenters make a variety of points about the uniqueness of these areas, EPA has received no information confirming that they are so different that the criteria should not be applied in those areas. Sites studied in the Great Lakes exhibit temperature profiles similar to those in Washington or Oregon. While no sites were in tropical areas, EPA is investigating the possibility of conducting future studies in a variety of temperature and geographical regimes.

EPA is promulgating the same criteria values as are in the 1986 bacteria criteria; today's rule does not establish different illness rates than those included in the 1986 bacteria criteria document.

## **Issue: California**

**Organization Name:** California Regional Water Quality Control Board

**Document ID:** 203

**Comment ID:** 92

**Comment:**

Beaches in the Los Angeles area are world-renowned and an icon of the region. Beaches such as Surfrider in Malibu and Santa Monica Beach at the Santa Monica Pier have become international destinations. On average, 55 million people visit beaches along the Santa Monica Bay each year--ranking them among the most heavily used beaches in the nation and in the world. These beaches are a valuable resource, generating tremendous revenue for the local and state economy.

Given the importance of LA's beaches, the Los Angeles Regional Board acted quickly to comply with the BEACH Act of 2000, adopting bacteria criteria consistent with US EPA's 1986 recommended criteria in 2001. The US EPA, Region IX approved the bacteria criteria on September 25, 2002. As a result, the US EPA is including California in the proposed rule, except for waters covered by the Los Angeles Region's approved bacteria objectives. Though the proposed rule will not have a direct impact on the Los Angeles Region, we strongly believe that it is important to have statewide consistency in bacteria standards for coastal waters.

**Organization Name:** California Regional Water Quality Control Board

**Document ID:** 203

**Comment ID:** 448

**Comment:**

Given the importance of LA's beaches, the Los Angeles Regional Board acted quickly to comply with the BEACH Act of 2000, adopting bacteria criteria consistent with US EPA's 1986 recommended criteria in 2001. The US EPA, Region IX approved the bacteria criteria on September 25, 2002. As a result, the US EPA is including California in the proposed rule, except for waters covered by the Los Angeles Region's approved bacteria objectives. Though the proposed rule will not have a direct impact on the Los Angeles Region, we strongly believe that it is important to have statewide consistency in bacteria standards for coastal waters.

The Los Angeles Regional Board's comments and suggestions, which are focused on the use of the single sample maximum values as criteria, are discussed below. Comments are separated by section location in the proposed rule.

**Organization Name:** California Regional Water Quality Control Board, San Diego Region

**Document ID:** 199

**Comment ID:** 121

**Comment:**

California is known worldwide for its beautiful shoreline and sandy beaches. For coastal cities (80 percent of the state's residents live with a 30 mile drive to the coast), the beaches are closely linked to the economy and way of life. Southern California beaches alone are estimated to receive 175 million visitors a year, spending over \$1.5 billion during their visits. Statewide, our beaches generate approximately \$17 billion a year in tourism revenue.<sup>2</sup> Such overwhelmingly high beach usage demands that we act in a conservative manner to protect our "world-famous beaches, [which] are an invaluable economic, environmental, and recreational resource..."<sup>3</sup>

**Footnote:**

<sup>2</sup>*California Beach Closure Report 2000*: July 2001. Division of Water Quality. State Water Resources Control Board. California EPA.

<sup>3</sup>*California Health and Safety Code*. Section 11590.

**Organization Name:** Tri-TAC

**Document ID:** 223

**Comment ID:** 433

**Comment:**

These comments are submitted on behalf of Tri-TAC in response to the Environmental Protection Agency's (EPA) proposed rule to establish water quality criteria for bacteria for coastal recreation waters. Tri-TAC is a statewide organization comprised of members from public agencies and other professionals responsible for wastewater collection and treatment in California. Tri-TAC is jointly sponsored by the California Association of Sanitation Agencies, the California Water Environment Association, and the League of California Cities. The constituency base for Tri-TAC collects, treats, and reclaims more than two billion gallons of wastewater each day and serves most of the sewered population of California.

As noted in your proposed rule, California is in an unusual position with regards to this proposal. For most coastal waters, as defined in the California Ocean Plan, total Coliform is the sole indicator used for the protection of water contact recreation. However, for beaches with over 50,000 visits per year, comprehensive beach sanitation standards have been adopted for public health protection purposes. These are not water quality standards, but they are used to make important public health decisions about whether or not beaches are open, closed or posted with an advisory against water contact recreation. Additionally, the Resources Control Board has proposed to adopt water quality objectives consistent beach sanitation standards. The proposal currently under consideration was made public on August 6, 2004, with a public hearing to consider the amendments scheduled for October 6, 2004.

**Response:**

For information on specific States and Territories, see the preamble to today's rule, in particular section V.B., Which States and Territories are Included in Today's Rule?

EPA agrees that it is important to have not only statewide but also national consistency for bacteria standards in coastal and Great Lakes waters with respect to protecting human health. EPA notes that this was one of the objectives of the Congress in passing the BEACH Act. (See S. Rep. No. 106-366(2000).)

EPA recognizes that some states regulate public bathing beaches through their Department of Health requirements. However, Section 303(i) of the Clean Water Act is clear that states must adopt recommended criteria into their water quality criteria and standards for coastal recreational waters that are as protective of human health as the EPA 1986 bacteria criteria. Moreover, States with BEACH Act implementation grants for monitoring and notification programs must use the applicable water quality standards, i.e., the water quality standards that protect the waterbody for swimming, bathing, surfing, or similar water contact activities.

EPA thanks the commenters who provided information on progress toward full compliance with the BEACH Act requirements.

## Issue: Compliance Schedule

**Organization Name:** Association of Metropolitan Sewerage Agencies

**Document ID:** 227

**Comment ID:** 289

**Comment:**

*New Discharges*

EPA's proposal limits the use of compliance schedules to "existing pathogen dischargers." Given that EPA often encourages CSO communities to relocate CSO outfalls in the context of long-term control plan (LTCP) implementation, AMSA requests that EPA clarify in the final rule that the definition of "new pathogen discharger" does not apply to relocated CSO outfalls.

**Organization Name:** City of New York Department of Environmental Protection

**Document ID:** 241

**Comment ID:** 55

**Comment:**

Two issues regarding implementation aspects of the proposed rule are of special interest to NYCDEP: compliance schedules and revised criteria.

### Compliance Schedules

The proposed rule requires that existing dischargers comply immediately with new or more restrictive water quality-based effluent limitations based on the Federal criteria for bacteria set forth. When this is infeasible, the dischargers may request approval from the permit issuing authority for a compliance schedule which may not exceed five years from the date of permit issuance, reissuance or modification, whichever is sooner.

NYCDEP has permits for a large number of combined sewer outfalls (CSOs), some of which could conceivably be affected by the final bacteria rule, depending upon its specific requirements. Under such a circumstance, we believe that it may be infeasible to comply with any such water quality-based limitations within the designated period. NYCDEP is presently implementing a series of CSO control programs with the cooperation and under the supervision, of the New York State Department of Environmental Conservation. Our experience has been that considerable effort and time is required to technically evaluate water quality-based effluent requirements, develop conceptual and detailed engineering plans, conduct required land use reviews and site acquisition, perform required environmental impact statements, obtain necessary regulatory approvals and finally construct the facilities.

Therefore, we request that the final rule give the permitting authorities the necessary flexibility to establish realistic and workable compliance schedules which allow for the required effort. In addition, we request that compliance requirements in the final rule be reconciled with those of the Wet Weather Water Quality Act of 2000 and the 1994 CSO Control Policy. In particular, we recommend that water quality-based permit compliance requirements for CSO impacted waters attendant to the final rule coincide with implementation of an approved CSQ Long Term Control Plan.

**Organization Name:** Florida Department of Environmental Protection  
**Document ID:** 229  
**Comment ID:** 80

**Comment:**

We recommend compliance schedules comparable to other water quality criteria changes. Normally in Florida permits are updated with new criteria as they come up for renewal.

**Organization Name:** Kansas Department of Health and Environment, Division of Environment, Bureau of Water  
**Document ID:** 173  
**Comment ID:** 202

**Comment:**

*Compliance Schedules* - EPA states "In instances where dischargers find that their current level of disinfection or other treatment is not sufficient to achieve the *E. coli* or enterococci criterion, dischargers will need to increase their current level of disinfection or evaluate and install new treatment technology." EPA has also stated previously that no approved test method exists for measuring *E. coli* in wastewater. Therefore, it seems unreasonable to expect NPDES permittees to establish whether their treatment is sufficient to meet an *E. coli* standard when no approved method for measuring *E. coli* in wastewater exists.

**Organization Name:** Louisiana Department of Environmental Quality  
**Document ID:** 169  
**Comment ID:** 325

**Comment:**

**Part 131 Subpart D, at 131.41 (f).** LDEQ has no objection to the use of compliance schedules for affected LPDES and NPDES dischargers.

**Organization Name:** Pennsylvania Department of Environmental Protection  
**Document ID:** 233  
**Comment ID:** 261

**Comment:**

PA DEP agrees with EPA's definition of a "new pathogen discharger" as any building, structure, facility or installation from which there is or may be a discharge of pathogens, and where the construction of which commenced after the effective date of the final rule. Existing pathogen dischargers would include sources currently discharging, those increasing dischargers, and new sources that had completed designing and initiated construction before the effective date of the final rule.

**Organization Name:** State of Ohio Environmental Protection Agency  
**Document ID:** 238  
**Comment ID:** 133

**Comment:**

I would like to take this opportunity to offer comments on Supplementary Information Section V.B. Compliance Schedules. Ohio EPA supports the use of compliance schedules to provide permitted dischargers time to meet effluent limits based on the proposed bacteria criteria. While Ohio has adopted rules that authorize the use of compliance schedules in our NPDES permits, and



so will not be subject to those provisions of the proposed rule, compliance schedules will be important to any state program implementing the proposed criteria in their NPDES permits.

Much like the proposed rule, Ohio's compliance schedule rule is based on the compliance schedule provisions of the Water Quality Guidance for the Great Lakes System (40 CFR 132). As such, we believe the definitions of new and existing pathogen dischargers will work well for implementing the rule.

**Organization Name:** State of Ohio Environmental Protection Agency

**Document ID:** 238

**Comment ID:** 135

**Comment:**

There is one provision that could needlessly complicate a State's efforts to implement this rule. The discharger should not be required to submit a request to the permitting authority to have a compliance schedule included in the NPDES permit. The permit writer should have the flexibility to evaluate the need for a compliance schedule based on available information, and it shouldn't depend on whether a request was received from the discharger. The provision that the discharger must request a compliance schedule is not part of the Water Quality Guidance for the Great Lakes System nor is it part of 40 CFR 122.47. We believe this provision should be deleted from the proposed rule.

**Organization Name:** The CSO Partnership

**Document ID:** 197

**Comment ID:** 413

**Comment:**

**EPA Cannot Impose an Arbitrary Limit on Compliance Schedules.**

Schedules are Necessary and Appropriate. We believe compliance schedules are absolutely appropriate for use with the new criteria. EPA's own November 2003 guidance acknowledges that POTWs using chlorine are likely to have a harder time meeting the new enterococci criteria, for example, than fecal coliform. November 2003 Guidance at 4.2.1

Moreover, we understand that side-by-side comparisons at a number of POTWs reveal that meeting the significantly lower *E. coli* and enterococci geometric means will be more difficult than the current fecal coliform requirements. Chicago, Illinois and Parkersburg, West Virginia are examples where *E. coli* ratios around 80-85% have been seen. This means that changing from a monthly geometric mean of 200 (fecal) to 35 (enterococci) will be a much more stringent requirement.

**Organization Name:** The CSO Partnership

**Document ID:** 197

**Comment ID:** 415

**Comment:**

**EPA Cannot Impose an Arbitrary Limit on Compliance Schedules.**

Please also note in the schedule section of the draft rule the discussion of the term "new discharger." The "new discharger" definition has the potential to interfere with the "sensitive area" requirements of the Wet Weather Water Quality Act of 2000. The relocation requirement of

CSOs discharging to sensitive areas in CWA Section 402(q) should be clarified as not resulting in a new discharge under this rule. Obviously, a relocation of a CSO discharge under 402(q) would not allow compliance with the new bacteria criteria from the moment of relocation. Such relocated CSO discharges must not be considered "new discharges" for the purposes of this rule.

**Organization Name:** Tri-TAC

**Document ID:** 223

**Comment ID:** 432

**Comment:**

Tri-TAC strongly endorses EPA's recommendation to States to allow for and include compliance schedules in adopting EPA's standards for bacteria. EPA should keep the provision authorizing compliance schedules in its final rule recognizing that dischargers may need time to come into compliance with a new or more stringent standard once it is translated into effluent limitations.

**Response:**

See the preamble to the rule, in particular section IV.D. Compliance Schedules.

EPA disagrees that it is unreasonable to expect NPDES permittees to establish whether their treatment is sufficient to meet an *E. coli* standard when no approved method for measuring *E. coli* in wastewater exists. Other commenters (in specific see comments from the CSO Partnership) have pointed to instances where POTWs have conducted side-by-side comparisons of fecal coliform concentrations to *E. coli* or enterococci concentrations. EPA Methods 1103.1, 1106.1, 1600, and 1603 for measurement of *E. coli* and enterococci do exist and have been subjected to interlaboratory validation in an assortment of disinfected wastewater matrices. POTWs can use these methods to reliably measure *E. coli* or enterococci concentrations in wastewater.

## **Issue: Cruise Ship**

**Organization Name:** State of Hawaii Department of Health/Environmental Health Administration

**Document ID:** 195

**Comment ID:** 396

### **Comment:**

**Cruise Ship Discharges:** The question of how the proposed rules will affect the cruise ship industry needs to be addressed. The federal Alaska cruise ship rules use fecal coliform standards. While DOH may not have jurisdiction over marine sanitation devices, we do have a strong interest and regulatory authority over the quality of receiving waters within the State's three-mile limit.

### **Response:**

Coastal recreation waters, as defined in section 502 of the Clean Water Act, include marine waters designated by a State or Territory for use for swimming, bathing, surfing, or similar water contact activities. This final rule establishes water quality criteria for bacteria for coastal recreation waters in specific States and Territories in which cruise ships may operate, including those in the State of Alaska and portions of the waters in the State of Hawaii; however, it does not affect existing requirements for regulation of cruise ship waste streams. In response to an administrative petition, EPA is evaluating the broad array of statutory and regulatory authorities that may apply to the various waste streams from cruise ships, including various provisions of the Clean Water Act, the Clean Air Act, the Resource Conservation and Recovery Act, the Act to Prevent Pollution from Ships, International Conventions and Treaties to which the United States is a party, and other provisions of law.

This comment specifically asks about regulation of certain cruise ship discharges in Alaskan waters. On December 12, 2000, Congress passed H.R. 4577, 'Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2001', which contained Title XIV, a section called 'Certain Alaska Cruise Ship Operations'. This law regulates the discharge of sewage and gray water from cruise ships authorized to carry 500 or more passengers for hire operating in the waters of the Alexander Archipelago and the navigable waters within the State of Alaska and within the Kachemak Bay National Estuarine Research Reserve. Before this law was passed, there was considerable concern about cruise ships discharging untreated sewage and gray water into areas that were surrounded by Alaskan waters but that are beyond three miles from shore. In these areas, known as doughnut holes, the discharge of sewage had not been effectively regulated, even though such discharges posed similar threats to regulated sewage discharges. Title XIV sets requirements for discharges of sewage and gray water into Alaskan waters and the doughnut holes and authorizes EPA to also develop regulations. To implement Title XIV, EPA is currently in the process of developing standards for discharges of black and gray water from cruise ships into Alaskan waters and expects to propose regulations in 2006.

## **Issue: Data Supporting Use of Fecal Coliform**

**Organization Name:** Kansas Department of Health and Environment, Division of Environment, Bureau of Water

**Document ID:** 173

**Comment ID:** 200

**Comment:**

*Are Standards Based on EPA's Recommended Indicators* - EPA solicited comment on other pathogen indicators that would be protective of public health. Based on a recent USGS study (Water-Resources Investigations Report 03-4056), a strong correlation exists between *E. coli* and fecal coliform bacteria in surface waters. Based on the correlation, a ratio between fecal coliform bacteria could be used to estimate equivalent concentrations of *E. coli*. Therefore, it should be possible to estimate risks associated with fecal coliform bacteria, based on risks associated with *E. coli*.

**Response:**

EPA appreciates the commenter that directs EPA to USGS report 03-4056. This report is titled Comparison and Continuous Estimates of Fecal Coliform and *Escherichia Coli* Bacteria in Selected Kansas Streams, May 1999 Through April 2002. While the information in the report may prove useful to the State of Kansas in revising its bacteria criteria, because the information is specific only to inland waters in Kansas, EPA does not consider the information in the report to provide sufficient information to develop such a relationship in either the Great Lakes or coastal marine waters, which are the subject of today's rule.

## Issue: Delaware

**Organization Name:** State of Delaware Department of Natural Resources and Environmental Control

**Document ID:** 211

**Comment ID:** 271

**Comment:**

The purpose of this letter is to request that the State of Delaware be removed from the Water Quality Standards for Coastal and Great Lakes Recreation Waters. Based upon the supplementary information provided in Section IV relative to Delaware's Standards, EPA has used outdated information as the basis for including Delaware in the Rule. Updated information is provided below.

The basis for the inclusion of Delaware in the proposed rule is the evaluation of Delaware's Surface Water Quality Standards as amended in 1999 versus the currently acceptable water quality criteria for marine beach waters. On July 11, 2004, Delaware promulgated revised Standards consistent with those criteria that provide the level of public health protection as specified in the Clean Water Act and in line with the requirements of the Beach Act. Specifically, Delaware adopted a geometric mean enterococci criterion of 35 CFU/100 mL and a single sample maximum (SSM) of 104 CFU/100 mL for marine waters. These criteria apply to fecal enterococci of non-wildlife origin. Throughout the adoption process, Delaware's new standards have been fully supported by EPA, both orally by Headquarters (Standards and Health Protection Division, Office of Science and Technology) and in writing by Region 3 (Attachments A 1-3). In addition, Ben Grumbles' letter of April 19, 2004 to Secretary John A. Hughes supported Delaware's standards and beach monitoring efforts (Attachment B). I was surprised and remain troubled by the inclusion of Delaware in the proposed rule.

Delaware makes the distinction of fecal enterococci of non-wildlife origin because it believes that the risk associated with fecal matter of wildlife origin presents a lower risk than that of fecal matter of human origin. Delaware concedes that pathogenic protozoa (*Cryptosporidium*, *giardia*) or bacteria (*E. coli* O157, *salmonella*) may be present in fecal matter of wildlife origin, but the majority of virus

**Organization Name:** State of Delaware Department of Natural Resources and Environmental Control

**Document ID:** 211

**Comment ID:** 272

**Comment:**

Example: The geometric mean of indicator bacteria in a waterbody is determined to be 47 CFU/100mL. Using BST, it is determined that bacteria of non-wildlife and unknown origin represent  $38 \pm 7\%$  of the total found within this watershed (Figure 1). Bacteria originating from human, domestic animal, farm animal and unknown sources are considered to have the highest risk level and are not discounted. The risk associated with the remaining bacteria, those originating from wildlife sources, is adjusted using the STAF. The  $STAF = 0.38 + 0.07 + 0.05 + [1 - (0.38 + 0.07)] * 35/155 = 0.62$ . The raw count (47 CFU/100mL) is multiplied by the STAF (0.62) to generate an adjusted count (29) that management decisions are based upon.

The use of the STAF allows Delaware to base public health decisions on a more precise level. The numbers used in determining the STAF have a scientific basis. The accuracy of the BST

methodology and threshold (Myoda et. al., 2003, Attachment C) has been published. In addition, Delaware has comprehensive land use, point source inventories, and sanitary surveys to double check the BST results to ensure they are appropriate. The geometric mean and SSM multipliers (35/155, 104/2212) used in the equation component representing risk from fecal matter originating from wildlife are based on a mini epidemiological study that correlated illness rates versus bacteria concentrations in Delaware in swimming areas that have no human fecal discharges. This study was submitted to the EPA in 1997 (Attachment D) and had been the basis for the beach criteria prior to the recent adoption of amended Surface Water Quality Standards. Currently, Delaware is working with the EPA on a pilot project using the STAF adjusted concentrations to base beach management decisions on two of Delaware's tier two beaches. In instances where a STAF is not available, the total, raw count is used.

Delaware believes that the recent adoption of its new standards, along with the use of BST and the STAF, represent a comprehensive approach that is protective of public health and is consistent with all Federal requirements. The EPA has been completely aware and supportive of Delaware's new standards throughout the adoption process. For these reasons, Delaware reiterates its position that it should be removed from the proposed Water Quality Standards for Coastal and Great Lakes Recreation Waters.

**Response:**

See the preamble to today's rule, in particular section V.B., Which States and Territories are Included in Today's Rule? for information on Delaware.

## Issue: Dual Standards

**Organization Name:** Buckeye Florida

**Document ID:** 172

**Comment ID:** 242

**Comment:**

*Application in Addition to any State/Territory Criteria* - Buckeye is supportive of EPA's expectation that States/Territories remove fecal coliform and other supplemental indicators previously adopted to protect primary contact recreation.

**Organization Name:** King County Department of Natural Resources and Parks

**Document ID:** 204

**Comment ID:** 333

**Comment:**

The use of an enterococcus standard in estuaries to evaluate water quality creates a disconnect between impact and source for the FC in shellfish growing waters at the terminus freshwater bodies. There is clearly a conflict in data interpretation if recreational water is adjacent to a shellfish growing area. The pragmatic reality is that if the stream or river actually is impacting shellfish growing waters and ultimately the shellfish industry, the monitoring programs will not provide the necessary information to recognize or pinpoint the source of the contamination. It is important to point out that the more restrictive FC limit of 14/100 ml was designed with the knowledge that shellfish are sessile filter feeders, and will concentrate bacteria from the water into their bodies. This limit was developed in an effort to enable shellfish to meet a tissue limit of 220 fecal coliforms per gram of meat. Even though EPA has stated that they expect FC testing will have to continue to address the shellfish standards, the concern is that with dwindling resources the frequency and number of sampling events may well become very limited, therefore while some simultaneous data may be collected, it may not be enough for strong source tracking.

Enterococci have different characteristics from fecal coliforms or even *E. coli* in the environment. There will be a major loss in data analysis and trends analysis for purposes of evaluating long-term environmental quality as FC sampling becomes more limited.

**Organization Name:** South Carolina Department of Health and Environmental Control Bureau of Water

**Document ID:** 161

**Comment ID:** 225

**Comment:**

**Issue:** Statement retaining the fecal coliform indicator.

This notice states that the EPA has no intentions of rescinding the fecal coliform bacterial indicator for these waters. This means that two indicator species will be required in perpetuity unless EPA makes the effort to address this issue with the FDA.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 358

**Comment:**

**Washington Should be Removed from the Final Rule**

The total increase in sampling and analytical costs to include enterococci along with fecal coliform in our marine waters is significant. Given that duplicative bacterial monitoring is not needed to ensure both shellfish harvesting and water contact recreation are fully protected, applying the enterococci criteria along with the shellfish harvesting criteria would be a waste of the state's limited financial resources. Having to monitor for both indicators in the face of limited budgets would also likely result in less samples overall being analyzed for bacterial pollution. It may also mean that other important water quality parameters would be dropped from sampling programs so that both bacterial indicators can be analyzed. We urge EPA to carefully consider our situation and to remove Washington from the final federal rule.

**Organization Name:** William Hastback

**Document ID:** 157

**Comment ID:** 302

**Comment:**

Finally, the move to enterococcus standards will cause a mismatch between databases developed by agencies that monitor bathing beach water quality and those that monitor water quality in shellfish growing areas, which could be the very same waters. Why is this a problem? Simple, if a health department that monitors bathing beach water quality contacts the shellfish sanitation program in a state to advise them that a particular bathing beach or permitted discharge fails to meet enterococcus standards the shellfish sanitation program will have no idea what that means with respect to the risk it creates for shellfish harvesting areas in proximity to that bathing beach. Conversely, just because a bathing area or permitted discharge meets the proposed enterococcus standards does that mean there is no health risk for nearby shellfish harvest areas?

**Response:**

See the preamble to today's rule, in particular section IV.C., Applicability of Today's Rule.

Today's rule applies to coastal recreation water, i.e., those marine and Great Lakes waters designated for primary contact recreation uses. Today's rule does not establish criteria for shellfish uses. The statement referred to by the commenter about EPA's intention to not rescind fecal coliform in coastal recreation waters refers to the fecal coliform criteria to protect primary contact recreation uses.

This rule does not require States and Territories to monitor their waters for *E. coli* or enterococci. EPA recognizes that many states have monitored their waters for a single indicator (i.e., fecal coliform) to determine the suitability of the waters for two uses (i.e., shellfishing and recreation) and, therefore, States and Territories that want to continue monitoring their waters to protect both uses will need to monitor for two indicators, i.e., fecal coliform to protect shellfishing and *E. coli* and/or enterococci to protect primary contact recreation. However, EPA would like to remind commenters that the Agency provides funding for beach monitoring and notification programs to all 35 States and Territories with coastal recreation waters. These grants will help offset any additional costs associated with monitoring for two indicators where the shellfishing and recreational designated uses overlap. Additional information on costs, particularly analytical method costs for enterococci enumeration, are included in the Economic Burden section of this document.



## Issue: Economic Burden

**Organization Name:** Massachusetts Water Resources Authority

**Document ID:** 245

**Comment ID:** 468

**Comment:**

It is worth noting that EPA has had these proposed criteria on the books for almost 20 years, yet has not approved a method for measuring enterococcus in wastewater. The focus of enterococcus as a pathogen indicator has been limited primarily to bathing beaches. It is premature to allow promulgations of new enterococcus limits for wastewater when little or no background information exists to assist in implementation. Two challenges identified by MWRA are as follows:

Because enterococcus is more resistant to chlorine than fecal coliform, this represents a change in treatment approaches to meet an enterococcus limit for dischargers that treat wastewater effluent with chlorine. Based on several years of voluntary enterococcus monitoring of MWRA wastewater, sodium hypochlorite dosage would need to increase by approximately 15% in order to meet the geometric mean enterococcus limit of 35 col/100 mL. This increase in total chlorine residual concentration after disinfection-even with subsequent dechlorination-may result in increases in disinfection/dechlorination operating costs, increased toxicity to marine organisms, and difficulties in meeting existing toxicity limits.

**Response:**

EPA Methods 1103.1, 1106.1, 1600, and 1603 have been subjected to interlaboratory validation in an assortment of disinfected wastewater matrices. The validation reports will for Methods 1600 and 1603 will be issued in late 2004, and in late 2005 for Methods 1103.1 and 1106.1. In addition, these methods will be modified for use in wastewater and will include all appropriate quality control parameters, and will be available at the same time as their respective validation reports. Method validation studies typically include several representative matrices and are not intended to include every potential effluent matrix to which a method may be applicable.

Experiences from facilities currently meeting the *E. coli* and enterococci criteria, as well as the current fecal coliform criteria, and literature data regarding concentration and inactivation of these bacteria, suggest that chlorination processes can be upgraded or adjusted to produce the levels of bacteria necessary for compliance with the rule. In its analysis of potential costs, EPA estimated that optimization of existing disinfection processes, including increasing chlorine dose, adding contact basins to increase contact time, and improving mixing conditions, would enable the facilities to comply with the final rule.

Increasing chlorine dose for compliance with the new bacteria criteria should not be necessary if other parameters are optimized, such as improving mixing conditions, increasing basin cleaning frequency to prevent build up of organic matter on chlorination tank walls, and increasing contact time so that the chlorine is consumed prior to discharge. If chlorine dose is increased, and the additional improvements listed above do not prevent an increase in residual chlorine concentrations, improvements in dechlorination may also be necessary. However, the cost of such dechlorination improvements (e.g., increasing dechlorination chemical doses) would be relatively minimal compared to chlorination process optimization costs.

## **Issue: Economic Burden 1**

**Organization Name:** People for Puget Sound

**Document ID:** 242

**Comment ID:** 34

**Comment:**

While the state may continue to require some monitoring for fecals, the cost of performing monitoring for both indicators could result in less fecal monitoring overall, which we view as a step backwards.

**Response:**

The rule does not require monitoring. States and Territories have flexibility to chose who will monitor, what they monitor for, and how often they monitor.

## Issue: Economic Burden 2

**Organization Name:** Pacific Coast Shellfish Growers

**Document ID:** 164

**Comment ID:** 72

**Comment:**

Under the Regulatory Flexibility Act, EPA must assess the impacts of their rulemaking on small businesses and governmental jurisdiction. EPA asserts that this rule will "*not have a significant economic impact on small entities*;" and that the rule "*establishes no requirements applicable to small entities*." This is categorically inaccurate. Washington State's Department of Ecology has submitted an economic analysis that shows the high estimated cost of applying dual standards (enterococcus and fecal coliform) to water quality. There will be significant costs incurred in monitoring for both these indicators, and more than likely this cost would be passed on to shellfish farmers to assure they continue to meet the stringent standards under the NSSP. The EPA has failed to take this into account.

The EPA incorrectly asserts that the proposed rule will have no impact on Tribal governments, and as such has failed to prepare a small government agency plan under section 203 of the Unfunded Mandates Reform Act. In fact, several Tribes in Washington and Alaska are involved in shellfish farming, which is an important source of family wage jobs. When the cost of conducting dual water quality monitoring programs must be passed on, the tribes will indeed be affected.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 390

**Comment:**

**VI. C. Paragraph 3:** EPA needs to consider the reality that there are costs imposed on small private and governmental entities. The water quality standards create a direct obligation on permit holders and others to monitor and comply. This is a very obvious pass through cost that is being wrongly dismissed.

**Response:**

The rule does not require monitoring. States and Territories have flexibility to chose who will monitor, what they monitor for, and how often they monitor.

Section 202 of the Unfunded Mandate Reform Act (UMRA) applies only if the rule would result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more. This rule does not impose such a level of expenditures on these entities. EPA estimates the annual cost of today's rule is \$20,000,000. Section 203 of UMRA calls for a small government agency plan before EPA establishes any requirements that may significantly or uniquely affect small governments. EPA has determined that today's rule does not include any such requirement because, as explained in the Economic Analysis accompanying today's rule, the annual costs associated with this rule will be below the \$100,000,000 threshold.

The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq., generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency

certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations and small governmental jurisdictions.

After considering the economic impacts of today's rule on small entities, EPA determined that this action will not have a significant economic impact on a substantial number of small entities. As discussed below, these water quality standards do not directly apply to any discharger, including small entities.

In the "Economic Analysis for Final Water Quality Standards for Coastal Recreation Waters," EPA presents an analysis which supports a conclusion that today's rule will likely affect only a few small entities.

## Issue: Economic Burden 3

**Organization Name:** Milwaukee Metropolitan Sewerage District

**Document ID:** 196

**Comment ID:** 189

**Comment:**

We believe that your estimate of a total of 850 potentially affected facilities **understates the cost impact** of this proposed rule. As the rule preamble notes, States or Territories "may decide to require controls for nonpoint sources (*e.g.*, agricultural runoff) or point source discharges (*e.g.*, CSOs and SSOs) due to wet weather events. However, as a technical matter, these sources are difficult to model and evaluate with respect to potential costs impacts because they are intermittent, highly variable, and occur under different hydrologic or climatic conditions than continuous discharges from industrial and municipal facilities, which EPA evaluates under critical low flow or drought conditions." Therefore, these types of sources are not included or addressed in the economic analysis for the rule. Yet, these difficult-to-model sources are the most significant contributors to pathogen load in many, if not all, receiving waters. To ignore these significant sources in the economic analysis of the rule is an approach which distorts the impact of the proposed rule, and which continues to place the burden of pathogen reduction on sources which do not contribute the lion's share of the load. Some effort must be made to address these sources in the economic analysis.

**Response:**

EPA addresses discharges of bacteria from municipal separate storm sewer systems, CSO, and SSO to coastal waters in existing regulations and policies, and has tallied potential control costs as part of the analyses for those actions. EPA expects that States and municipalities will continue to use the same types of controls to come into compliance with the revised criteria as are currently used for compliance with existing regulations and policies. In general, the best management practices or treatment controls for wet weather discharges that are used to attain fecal coliform standards in a waterbody are also the best management practices or treatment controls used to address *E. coli* and enterococci. Because of the substantial variability in bacterial indicators and the site-specific effectiveness of control measures, EPA is not able to determine at this time if additional measures will ultimately be necessary to meet criteria based on the new indicators. Compliance with pathogen standards is best achieved through an adaptive management approach based on cost-effective management practices and control measures coupled with on-going monitoring and revision of control strategies as necessary.

The fecal coliform standard includes a geometric mean and a maximum value that is not to be exceeded in more than 10% of observations. This rule does not require SSMs as "never-to-exceed" values for Clean Water Act purposes other than beach monitoring. Therefore, EPA believes that the 1986 bacteria criteria for enterococci and *E. coli* will not have an incremental cost impact associated with nonpoint sources or wet weather point source events because it is no more stringent than the current fecal coliform standard.

## Issue: Economic Burden 4

**Organization Name:** Pennsylvania Department of Environmental Protection

**Document ID:** 233

**Comment ID:** 266

**Comment:**

In Section VI, Economic Analysis, EPA states that "it is likely that any controls needed to meet existing (i.e., based on fecal coliform) would also address any quality problems indicated by standards based on *E. coli* or enterococcus." We are not aware of data that support this statement, and given the lack of correlation demonstrated between *E. coli* and fecal coliform densities in duplicate samples, we question the accuracy of assuming the cost will be comparable to controlling fecal coliform. It is important to be aware of the costs of this regulation on discharges and we request EPA to provide a definitive answer.

**Response:**

The statement in the Economic Analysis refers to BMPs for nonpoint sources and wet weather discharges. The discussion in the Economic Analysis lays out the methodology that EPA used to compare the efficacy of treatment for fecal coliform and other bacterial pathogen indicators, along with the references cited. It was this information that EPA used to state that controls implemented for compliance with the current fecal coliform standards would also most likely result in compliance with the 1986 bacteria criteria for enterococci and *E. coli*.

## Issue: Economic Burden 5

**Organization Name:** Association of Metropolitan Sewerage Agencies

**Document ID:** 227

**Comment ID:** 290

**Comment:**

*EPA's Economic Analysis Fails to Assess Key Cost Considerations*

EPA's economic analysis for the proposed rule assumes EPA will promulgate the geometric mean. However, the real cost associated with this rulemaking will be affected by the final interpretation of the term "single sample maximum." If EPA applies the SSM as a never to exceed value, virtually any waterbody with a measurable amount of urban runoff, not to mention a CSO-impacted waterbody, will not be able to fully attain the criteria. AMSA believes that if EPA applies the SSM as a never to exceed value, the Agency must redo its economic analysis accordingly and re-propose the criteria.

EPA's existing economic analysis is problematic because it does not directly estimate the costs associated with the control of municipal separate storm sewer systems (MS4), CSOs, and sanitary sewer overflows (SSOs). EPA indicates that "these sources are difficult to model and evaluate with respect to potential costs impacts." EPA does, however, address these discharges in "existing and anticipated regulations and policies, and has tallied potential control costs as a part of analyses for these actions" in the proposed rule.

EPA's economic analysis primarily evaluated the ability of wastewater treatment plant effluent to comply with the new standards, specifically the geometric mean. EPA indicates that chlorination processes can be upgraded or adjusted to produce the levels of bacteria necessary for compliance with the proposed rule. AMSA's members have indicated, for the most part, that for a full secondary treatment plant, EPA's characterization, that disinfection process optimization should be sufficient, is accurate. However, plants that are not at full secondary, for example wet weather treatment facilities at CSO outfalls, may have more difficulty meeting the new standards. The costs associated with bringing these facilities into compliance with EPA's final standards should be considered

**Organization Name:** Association of Metropolitan Sewerage Agencies

**Document ID:** 227

**Comment ID:** 291

**Comment:**

*Implications for CSO Communities*

A closer examination of the supporting document, *Economic Analysis for Proposed Water Quality Standards for Coastal Waters* (June 2004), reveals that, with respect to CSOs, EPA has "accounted for the potential costs of these controls in its report to Congress" on CSOs in 2001. The stated national CSO needs figure of \$44.7 billion was based on the 1996 Clean Watersheds Needs Survey Report to Congress - *Assessment of Needs for Publicly Owned Wastewater Treatment Facilities, Correction of Combined Sewer Overflows, and Management of Storm Water and Nonpoint Source Pollution in the United States*. The Report to Congress and the underlying needs survey, however, did not take into consideration EPA's proposed narrow interpretation of the SSM. There is no evidence that the standard to which CSOs were held in

these needs estimates (the equivalent of primary clarification and disinfection) would ensure compliance with a SSM for bacteria.

In fact, preliminary estimates by one AMSA member in the Great Lakes region indicate that CSO construction to support the SSM criteria will increase costs by approximately 60%, or nearly a billion dollars, without considering O&M costs. Thus, this regulation would result in an annual capital expenditure by just one Great Lakes discharger of more than the proposal's \$7,000,000 estimate for all Great Lakes dischargers.

Should EPA adopt the SSM as a never to be exceeded water quality standard, CSO communities would have no choice but to eliminate all overflows to meet the standard. During the CSO LTCP development process, most wastewater treatment agencies evaluate the costs associated with achieving zero overflows (i.e., sewer separation) as compared to the cost of achieving 4-6 overflows per year. AMSA informally polled its CSO members to assist in preparing these comments, and found that the costs to achieve zero overflows for many communities were staggering when compared to their existing plans geared to some remaining overflows:

Midwest - A large discharger (greater than 100 MGD) estimates its costs would climb from \$3.8 billion to \$20 billion if forced to achieve full separation.

Northeast -

- A large discharger (greater than 100 MGD) estimates its current cost estimate would increase by \$3 to \$5 billion, if complete elimination of overflows was required.

- A medium-sized discharger (less than 20 MGD) estimated a nearly six-fold increase in cost from \$42.5 million to \$250 million to achieve full separation.

We do not believe that EPA would intend to impose such dramatic costs on public agencies, and are confident that this result is inconsistent with Congress' intent in endorsing the process for CSO communities outlined in the CSO Policy. Achieving zero overflows through sewer separation will only ensure that CSOs are no longer contributing to the problem. In the end, the waterbody will still not be able to meet the "never to exceed SSM" standard due to stormwater impacts, which will be exacerbated by sewer separation.

**Organization Name:** King County Department of Natural Resources and Parks

**Document ID:** 158

**Comment ID:** 421

**Comment:**

We at King County in Washington State have significant concerns about this action and want to comment on the options EPA are considering. In each part of the rule EPA is asking for comment on has significant issues, not the least of which is the application of a single sample maximum along with a geomean. For any utility or municipality in the midst of long term control plan for CSOs, it can be assured that for a few hours periodically, there will be opportunities to exceed the standards being proposed. Such exceedances would lead to listing of waterbodies and TMDLs solely on the exceedance of that single daily maximum. This is not wise policy or appropriate use of EPA's override of state delegated authority, particularly when the states will be the ones that will have to prepare the TMDLs such actions would necessitate.



**Organization Name:** Northeast Ohio Regional Sewer District

**Document ID:** 198

**Comment ID:** 307

**Comment:**

**The EPA cost analysis greatly underestimates the proposed rule's impact.**

*CSOs and SSOs*

In Section VI, Economic Analysis, EPA states that the Agency "did not estimate costs for such [combined sewer overflow and sanitary sewer overflow] discharges for this rule," averring that omitting them would "avoid double counting." In justification, EPA states that it "has tallied potential control costs as part of analyses for" them in analyzing other "existing and anticipated regulations and policies."

No specifics are included in the proposal for these statements; however, one of the supporting documents, *Economic Analysis for Proposed Water Quality Standards for Coastal Waters* (June 2004), provides more insight. With respect to CSOs, the analysis states that "EPA accounted for the potential costs of these controls in its report to Congress" on CSOs in 2001. That report, in turn, states that "data from EPA's 1996 Needs Survey sets national CSO needs at \$44.7 billion (in 1996 dollars)."

The basis for that number is explained in the *1996 CWNS Report to Congress - Assessment of Needs for Publicly Owned Wastewater Treatment Facilities, Correction of Combined Sewer Overflows, and Management of Storm Water and Nonpoint Source Pollution in the United States*: "The cost curve methodology was based on the CSO Control Policy option that requires the elimination or capture for primary treatment of no less than 85 percent of the wet weather flow by volume ... The cost of the facilities required to provide additional treatment consisting of primary sedimentation, chlorine disinfection, and de-chlorination was then estimated with the cost curves."

In a more recent treatment, *Clean Watersheds Needs Survey 2000 - Report to Congress* (August 2003), a similar approach is described: "The ... estimate is primarily based on the level of control presented under the 'Presumption Approach' in the 1994 CSO Control Policy. That level of control is based on capturing 85 percent of the flows that enter the combined sewer system during wet weather events and providing those flows with the equivalent of primary clarification, solids and floatables disposal, and disinfection of the effluent."

**Organization Name:** Northeast Ohio Regional Sewer District

**Document ID:** 198

**Comment ID:** 308

**Comment:**

We take these statements to mean that both the 1996 and 2000 surveys used essentially the same methodology. Use of these cost estimates in the current context is inadequate. There are two reasons for this:

1) Our experience with EPA review of CSO facilities plans and long-term control plans indicates that the Agency does not consider that the goals stated in these two reports represent adequate levels of treatment for CSOs. The actual corrective measures espoused by reviewers will be significantly more expensive.

2) The CSO policy was drafted, and subsequent cost estimates were made, prior to the introduction of SSM criteria.

a) There is no evidence that "the equivalent of primary clarification, ... and disinfection of the effluent" will support the SSM as a value never to be exceeded. Given the difficulties in dealing with these wildly variable flows, there is every reason to believe that this approach will lead to water quality violations if judged based on SSM criteria.

b) The discharge remaining after "capturing 85 percent of the flows" will certainly cause or contribute to regular violations of the SSM criteria.

c) Preliminary estimates by the NEORSD indicate that CSO elimination to support SSM criteria within its own service area will increase costs by \$1.2 billion over the existing NEORSD plans to control CSOs. Thus, this regulation will result in an annual capital expenditure for a single Great Lakes discharger much greater than the \$7,000,000 estimate offered with the proposed rule for *all* Great Lakes dischargers.

Therefore, the Economic Analysis section for CSOs is grossly inadequate.

The cost estimates for sanitary sewer overflows ("SSOs") are as flawed as those for CSOs. As stated in the presentation of the year 2000 needs assessment, "The model [used to develop SSO needs] is based on reducing wet weather overflows within a collection system to one every 5 years." This obviously does not account for meeting SSM criteria. First, the proposed rule makes no provision for suspending the SSM requirement for extreme climatic events. Therefore, the model used by EPA to develop costs virtually guarantees that there will be violations. Second, in a large collection system, five-year return storms will not occur across the entire system *at the same time*, or even in the same year. Therefore, the events presupposed in the model will actually result in multiple occurrences in one watershed.

As demonstrated above, the cost analysis for both CSOs and SSOs is fatally flawed.

**Response:**

EPA disagrees that its analysis of POTWs did not include some wet weather considerations. In conducting its Economic Analysis for the rule, EPA selected at random POTWs from the coastal and Great Lakes areas. In this selection process, EPA did not screen out any POTW based on its receipt of wet weather flow. Some of the POTWs included in the analysis receive wet weather flows and thus were addressed in the analysis.

EPA recognizes the comments about the potential effect of the single sample maximum on effluent limits for CSO, SSO, and MS4 discharges. However, as discussed in section IV.B.3. of the preamble, other than for beach notification, the rule allows states the flexibility to use the single sample maximum for Clean Water Act implementation as long as the geometric mean criterion is achieved in the waterbody. Given state practice in implementing the current bacteria criteria, EPA does not expect that state permitting programs will apply the single sample maximum as an end-of-pipe effluent limit, which was the concern expressed by commenters.

## **Issue: Economic Burden 6**

**Organization Name:** Department of Environmental Services City and County of Honolulu

**Document ID:** 235

**Comment ID:** 293

**Comment:**

The Department of Environmental Services owns and operates four wastewater treatment plants that discharge treated wastewater through deep ocean outfalls. We will be significantly impacted if the proposed marine recreational water quality criteria are applied because we may be required to unnecessarily upgrade existing treatment processes or install new disinfection facilities. Our monitoring of the bacterial water quality and other WQS parameters in the vicinity of these outfall discharges for over 20 years continues to show no impact to recreational public health.

**Organization Name:** Department of Environmental Services City and County of Honolulu

**Document ID:** 235

**Comment ID:** 297

**Comment:**

**Impact to City and County of Honolulu**

The application of the 35 cfu/100 ml GM enterococcus standard to waters outside of 300 meters will be very costly to the City and County of Honolulu with no significant benefit. For many years, we have been complying with Section 11-4-8(b) of the WQS, which applies only to the waters inside 300 meters. Our NPDES permits require compliance with Section 11-4-8(b) and our receiving water monitoring programs include very intensive bacterial testing of shoreline and near shore waters. The health of beach users has not been impacted by our four deep ocean outfall discharges. Below is a detailed description of our four outfall systems and the specific cost impacts if the 35 cfu/100 ml GM limit is applied to waters up to 600 feet deep.

***Sand Island Outfall***

*Description:* Disposes of an average flow of 75 million gallons per day (mgd) of primary treated wastewater from the Sand Island WWTP, approximately 9,000 feet offshore at an average depth of 220 feet. Effluent is currently not disinfected but a UV disinfection facility is scheduled to begin operation in early 2005. A one-year bacterial study of the receiving waters will be conducted to determine the benefit and need for continuous disinfection.

*Impact:* We will not be able to comply with the 35 cfu/100 ml enterococcus GM average at the point of discharge. Effluent monthly GM averages for the Sand Island effluent currently range from 3.2x10E6 to 4.9x10E6 cfu/100 ml (July 2003-June 2004). The UV disinfection facility is designed to meet a maximum of 18,000 c.f.u./100 ml, as required by the NPDES permit. To meet the 35cfu/100 ml standard at point of discharge, we would have to construct secondary treatment to remove additional solids to allow the UV system to provide the required kill. Secondary treatment is estimated to cost \$450 million in capital costs and \$10 million in additional annual O&M costs.

### ***Barbers Point Outfall***

*Description:* Disposes of average flow of 22 mgd of primary treated wastewater from the Honouliuli WWTP, approximately 8,000 feet offshore at a depth of 200 feet. Effluent is currently not disinfected.

*Impact:* We will not be able to meet the 35 cfu/100 ml enterococcus GM criteria at the point of discharge. Effluent GM averages range from 276,355 cfu/100 ml to 575,249 cfu/100 ml (July 2003-June 2004). Estimated cost is \$90 million, which includes upgrade to secondary treatment to allow effective disinfection.

### ***Mokapu Outfall***

*Description:* Disposes of average flow of 18 mgd of secondary treated wastewater from the Kailua Regional WWTP, approximately 5,000 feet offshore at a depth of 100 feet. Effluent is currently disinfected by UV disinfection.

*Impact:* We will not be able to meet the 35 cfu/100 ml enterococcus GM criteria consistently at the point of discharge. Effluent GM averages range from 12 cfu/100 ml to 7,857 cfu/100 ml (July 2003-June 2004). The existing UV system may have to be upgraded to consistently meet the 35 cfu/100 ml GM criterion.

### ***Waianae Outfall***

*Description:* Disposes of average flow of 3.53 mgd of secondary treated wastewater from the Waianae WWTP, approximately 6,184 feet offshore at a depth of 105 feet. Effluent is currently not disinfected.

*Impact:* We will not be able to meet the 35cfu/100 ml enterococcus GM criteria at the point of discharge. Effluent GM averages range from 20,000 cfu/100 ml to 49,827 cfu/100 ml (July 2003-June 2004). A new UV disinfection system would have to be installed to meet the 35 cfu /100 ml. Estimated cost of a disinfection facility is \$2.0 million.

### **Response:**

EPA agrees that wastewater treatment plants with either primary or secondary treatment and no effluent disinfection will have difficulty meeting the enterococci criteria at the point of discharge (i.e., end-of-pipe with no allowance for dilution). However, today's rule does not require that the criteria be implemented as an end-of-pipe limitation. Hawaii's water quality standards generally allow for mixing zones, and all four outfalls identified in the comment currently are allowed to mix with ocean water before attainment of the criteria is ascertained. The current NPDES permits allow for mixing. Additionally, one of the treatment facilities (Sand Island) is already proceeding with disinfection, as a condition of its permit. Therefore, EPA does not expect that the four facilities identified in the comment will be required to achieve compliance with the criterion at the point of discharge.

In its Economic Analysis, EPA estimated costs for the sample facilities by conservatively assuming (i.e., erring on the side of higher costs) that the *E. coli* and enterococci criteria would be applied end-of-pipe (i.e., no dilution), unless site-specific data (e.g., approved mixing zones, etc.) indicate otherwise. However, EPA made this assumption in order to provide a conservative estimate of cost, and not because it is a requirement of the rule.

## Issue: Economic Burden 7

**Organization Name:** Association of Metropolitan Sewerage Agencies

**Document ID:** 227

**Comment ID:** 295

**Comment:**

*Additional Cost Considerations*

The model used to develop the SSO needs is based on reducing wet weather overflows within a collection system to one every five years, but again, the SSM criteria has not been considered.

The proposed regulation makes no provision for suspending the SSM requirement for extreme climatic events. Therefore, the model used by EPA to develop costs virtually guarantees that there will be violations.

In a large collection system, five year return storms will not occur across the entire system *at the same time*, or even in the same year. Therefore, the events presupposed in the model will actually result in multiple occurrences in one watershed.

In reference to total maximum daily loads (TMDLs), and state impaired water listings, the Economic Analysis document states:

There is no data to indicate that changing the bacterial indicator for coastal recreation waters from fecal coliform to *E. coli* and enterococci would result in any additional waters listed as impaired by pathogens, or in additional controls on sources to coastal recreation waters already listed as impaired by pathogens.

While this statement may be true, the document presents no evidence that the converse is not equally true.

Based on several years of voluntary enterococcus monitoring at one AMSA member facility (approximate average daily flow of 400 million gallons per day), sodium hypochlorite dosage would need to increase by approximately 15% in order to meet the geometric mean enterococcus limit of 35 col/100 mL. This increase in total chlorine residual concentration after disinfection, even with subsequent dechlorination, may result in increased toxicity to marine organisms, difficulties in meeting existing toxicity limits, and increases disinfection/dechlorination operating costs over \$200,000 per year.

In Appendix D of EPA's Economic Analysis the following statement

**Organization Name:** Northeast Ohio Regional Sewer District

**Document ID:** 198

**Comment ID:** 309

**Comment:**

*Other Economic Analysis Issues*

1) In reference to TMDLs and State impaired water listings, the Economic Analysis document states: "There is no data to indicate that changing the bacterial indicator for coastal recreation waters from FC to *E. coli* and enterococci would result in any additional waters listed as impaired

by pathogens, or in additional controls on sources to coastal recreation waters already listed as impaired by pathogens." While this statement may be true, the document presents no evidence that the converse is not equally true; i.e., it does not provide data that the change will not result in an increase in waters listed as impaired by pathogens.

2) The entire analysis ignores the SSM criteria except for wastewater treatment plant discharges. The above quote in reference to TMDLs is one clear sample.

3) In Appendix D, Energy Use, the following statement appears: "Increasing chemical (chlorine) dose: Involves allowing more chemical to flow through the pipes from pressurized vessels, or by gravity for liquid chlorine applications. EPA estimates that there is no incremental increase in energy use associated with this activity." The procedures described here are not used, because they are impractical, imprecise, and dangerous. In fact, liquid chlorine (which we presume to mean sodium hypochlorite, not liquid chlorine) is fed using metering pumps so that disinfection can be matched to the conditions, particularly flow, present at the time. In order to avoid the fatalities that could result from trying to directly diffuse gaseous chlorine into the effluent stream, a solution of water and chlorine is first prepared under controlled conditions. This solution is then mixed with the effluent. In either case, an increase in applied dose will result in increased pumping and therefore increased energy costs.

This solution is then mixed with the effluent. In either case, an increase in applied dose *will* result in increased pumping and therefore increased energy costs.

**Response:**

This action does not require SSMs as "never-to-exceed" values for Clean Water Act purposes other than beach monitoring. SSMs are values that, with a certain degree of confidence, indicate that a waterbody likely exceeds the geometric mean. The State can collect additional data on receiving water if it believes that the violation of the SSM does not indicate violation of the geometric mean. The BMPs for CSOs and MS4s that would enable attainment of the geometric mean for fecal coliform would also enable compliance with the rule. For facilities with numeric limits (e.g., CSO treatment facilities), States can calculate daily maximum values using the geometric mean criterion and EPA's TSD procedures (U.S. EPA, 1991), and those already meeting numeric limits for fecal coliform should have little trouble meeting limits for *E. coli*/enterococci. Thus, SSMs will not typically result in incremental costs above and beyond those already required to meet existing criteria/regulations.

The SSM values in today's rule may, but are not required to be used in developing NPDES permit limits. In its Economic Analysis, EPA assumed that SSM values would be incorporated into NPDES permits to give a conservative (high) estimate of costs that might be incurred from implementing the rule.

Available evidence indicates that if discharges are controlled in such a way that existing fecal coliform criteria are met, it is likely that enterococci and *E. coli* criteria would also be met (see response to the Economic Burden 14 comment code). EPA does not have data that indicates that the change in criteria will lead to additional waters being designated as impaired. (Also see response to the Burden 12 comment code).

EPA does not anticipate increased chlorine residual concentrations when dechlorination processes are operated properly. EPA has observed in NPDES permit compliance monitoring that publicly owned treatment works have had success in low concentrations of chlorine.

In estimating costs to sample facilities, EPA assumed that facilities would increase their chlorine dose from 4 mg/L to 8 mg/L, or by 100%. Applying these costs to a 400 mgd facility would result in an increase in operating costs of over \$3 million per year. Assuming that only a 15% increase in chlorine would be necessary for compliance, EPA estimates, based on the unit costs in its Economic Analysis, that operating costs would increase by about \$475,000 per year. Thus, EPA's estimated operating costs most likely overstate the actual costs that would be incurred by facilities to comply with this rule.

For larger, controlled systems (e.g., major POTWs), metering pumps may be necessary for chlorine delivery to ensure safety and prevent spills. However, for minor dischargers or variable discharges such as CSOs, the chlorine application process described in Appendix D of the Economic Analysis is a feasible and realistic alternative. Because enterococci may be more resistant under certain conditions to chlorination than fecal coliform, there may be slightly increased energy use in providing chlorination depending on the application process used. However, compared to the energy use of a typical treatment facility, the change would likely be negligible by monitoring of overall facility power consumption.

**Issue: Economic Burden 8**

Comments originally listed under this issue have been reassigned to another issue.



## Issue: Economic Burden 9

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 368

**Comment:**

The EPA rule should address additionally the costs associated with all the people who would be expected to fall ill because of states implementing the federal criteria. EPA has failed to engage in meaningful discussion with our state on this issue and we continue to find serious fault with the national criteria recommendations and the constantly changing federal implementation policies.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 383

**Comment:**

EPA has an obligation to include the costs of the additional sick people in its economic assessment on the costs of this rule and in doing so must examine the costs in total not just the additive costs of the proposed changes in the allowable disease rates. Examining compliance costs for a subset of dischargers is an inadequate form of economic analysis for a rule that allows large numbers of citizens to become sick. We know this is difficult, but if EPA is going to promulgate health standards they have an obligation to provide full disclosure on the effects of those rules on public health and the economy.

**Response:**

The risk levels on which the *E. coli* and enterococci criteria are based are the same as those on which the fecal coliform criteria were based. Thus, there will be no additional costs of illness associated with the rule. If a State or Territory believes that the criteria are insufficiently stringent to protect human health, it can implement more stringent criteria in its water quality standards.

## Issue: Economic Burden 10

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 389

**Comment:**

*Economic Analysis*

EPA has provided a very incomplete assessment of the costs associated with its rule. The absence of precise information on various topics is not a valid reason to completely exclude them from the analysis. Focusing on treatment costs to a subset of point source dischargers is entirely inadequate. For example, even for point sources there are increased laboratory costs associated with the need to have new equipment and reagents, and there is a need to monitor for two or three indicators to ensure compliance with downstream standards (which may be fecal coliform to protect shellfish harvesting and enterococci to protect swimming). Because of the need to comply with downstream standards, it is also not appropriate to limit the analysis to facilities located within two miles of marine waters. Further, general permits are waived off as if they will have no compliance problems without any factual basis provided to support this assumption. A small discharge to a swimming area or a small creek will likely have compliance problems.

Our EPA regional office is expecting general permits to be prepared in a manner that complies with water quality standards. This is also true of storm water, which is also left out of EPA's economic assessment. There are also the costs associated with the increase in illness rates in states such as Washington, where the EPA rule will result in less protective criteria. We understand the difficulty of conducting economic assessments on water quality standards and do not expect EPA to be able to definitively estimate the total costs. However, prior to EPA imposing a federal rule on a subset of states we expect a more sincere effort than what has been presented in the draft rule. We have previously sent EPA copies of a draft economic analysis that shows the high estimated costs of applying the EPA criteria in the state of Washington. A similar approach could be used by EPA to extend the cost estimates to the other impacted states.

**Response:**

EPA addresses discharges of bacteria from MS4s, CSOs, SSOs, and nonpoint sources (e.g., agriculture) to coastal waters in existing and anticipated regulations and policies, and has tallied potential control costs as part of analyses for these actions. Therefore, to avoid double counting, EPA did not estimate such costs for this rule.

The fecal coliform standard includes a geometric mean and a maximum value that is not to be exceeded in more than 10% of observations. The final rule also will not require SSMs as "never-to-exceed" values for Clean Water Act purposes other than beach monitoring. Therefore, EPA believes that the 1986 bacteria criteria for enterococci and *E. coli* will not have an incremental cost impact associated with nonpoint sources or wet weather point source events because it is no more stringent than the current fecal coliform standard.

The commenter did not provide data to support the claim that EPA should have evaluated waters further upstream, or for which waters EPA's assumption is unreasonable. Although the agency does not have specific models for different systems to determine the fate and transport of bacteria to coastal recreation waters, it believes that a 2-mile upstream radius is a large enough net for estimating the potential costs associated with the rule.

Data in PCS are extremely limited for general permitted facilities. Without location information such as latitude and longitude or receiving water body name, EPA cannot determine whether a facility is in the universe of potentially affected facilities. Therefore, EPA did not evaluate general permitted facilities in its Economic Analysis. Note, however, that data from the minor sample facilities evaluated in the Economic Analysis indicate that additional controls for general permitted facilities would most likely not be necessary for compliance with the *E. coli* and enterococci criteria. (Also see response to Comment ID 34 and 368).

## Issue: Economic Burden 11

**Organization Name:** The CSO Partnership

**Document ID:** 197

**Comment ID:** 411

### **Comment:**

#### **The Economic Analysis is Seriously Inadequate**

The economic analysis included in the pre-amble does not adequately represent the costs in the proposed rule. There are several areas of concern.

First, the proposed rule is contradicted by EPA's November 2003 guidance. An example is the cost impact from the new criteria. The proposed rule states:

"Finally, it is likely that any controls needed to meet existing standards (i.e., based on fecal coliform) would also address any water quality problems indicated by standards based on *E. coli* or enterococci."

We know this is not the case. For example, EPA's guidance acknowledges that POTWs using chlorine are likely to have a harder time meeting the new enterococci criteria...than fecal coliform. November 2003 Guidance at 4.2.1

Second, EPA admittedly ignored the costs to wet weather sources such as CSOs, SSOs, and municipal storm water dischargers. For example, the proposed rule admits:

EPA addresses discharges of bacteria from municipal separate storm sewer systems, combined sewer overflows (CSOs), and sanitary sewer overflows (SSOs) to coastal waters in existing and anticipated regulations and policies, and has tallied potential control costs as part of analyses for these actions. Controls for these types of discharges, which are not based on numeric limits are not likely to be substantially affected by the revised indicators in the proposed rule, at least in the near future. Therefore, to avoid double counting, EPA did not estimate costs for such discharges for this rule.

This is simply incorrect, especially if a UPV is imposed. In that case, municipal dischargers may be required to meet a daily maximum limit instead of a monthly or weekly limit as is the current practice in the majority of states. EPA should have calculated this significant additional cost or expressly stated that the costs were ignored because the UPV

### **Response:**

The statement, "Finally, it is likely that any controls needed to meet existing standards (i.e., based on fecal coliform) would also address any water quality problems indicated by standards based on *E. coli* or enterococci" refers to best management practices (BMPs) related to nonpoint sources and wet weather point source discharges. For point sources, the chlorination process at POTWs cannot be compared to the BMPs applicable to nonpoint sources and wet weather point source discharges because the control mechanisms for each source are fundamentally different. Chlorination at POTWs kills bacteria, whereas BMPs for nonpoint sources and wet weather discharges focus on reducing the volume of water discharged to receiving waters, thus, reducing the amount of bacteria as well. (Also see the response to the Economic Burden 1 comment code).

This action does not require SSMs as "never-to-exceed" values for Clean Water Act purposes other than beach monitoring. SSMs are values that, with a certain degree of confidence, indicate that a waterbody likely exceeds the geometric mean. The State can collect additional data on receiving water if it believes that the violation of the SSM does not indicate violation of the geometric mean. The BMPs for CSOs and MS4s that would enable attainment of the geometric mean for fecal coliform would also enable compliance with the rule. For facilities with numeric discharge limits (e.g., CSO treatment facilities), States can calculate daily maximum values using the geometric mean criterion and EPA's Technical Support Document procedures (U.S. EPA, 1991), and, based on the evaluation included in the Economic Analysis, those already meeting numeric limits for fecal coliform should have little trouble meeting limits for *E. coli*/enterococci. Thus, SSMs will not typically result in incremental costs above and beyond those already required to meet existing criteria/regulations.

The SSM values in today's rule may, but are not required to be used in developing NPDES permit limits. In its Economic Analysis, EPA assumed that SSM values would be incorporated into NPDES permits to give a conservative (high) estimate of costs that might be incurred from implementing the rule.

## Issue: Economic Burden 12

**Organization Name:** The CSO Partnership

**Document ID:** 197

**Comment ID:** 412

**Comment:**

Costs missing from the analysis include at a minimum the following:

- Costs to add effluent filters to all secondary POTWs impacting coastal recreational waters. While secondary plants with disinfection are adequate to meet the long-term geometric mean, UPVs applied at the end of pipe would in most cases require effluent filters.
- Costs to eliminate CSOs. Technology to disinfect CSOs is not reliable enough to meet a UPV criterion at the end of pipe. Eliminating CSO would move the problem to storm water where additional controls would also be required.
- Costs to provide for bacteriological controls for all MS4 permits must also be included if the UPVs are in the final rule as currently proposed.

Third, EPA alleges that it "does not have data to quantify the effects of the proposed rule on total maximum daily loads for pathogen-impaired waters." However, these impacts have been well-established by states that have already adopted EPA's new criteria. For example, attached is a regulatory notice detailing the financial impact in Virginia of its adoption of EPA's 1986 Bacteria Criteria in 2001. Virginia estimates that the criteria would trigger a 40% increase in bacteria TMDLs. Attachment at 4. This equated to a \$5.5 million increase in costs to Virginia to develop the additional TMDLs as well as a \$142 million cost to regulated entities implement those additional TMDLs. Id. Virginia also estimated another \$3-4 million per year increase in testing costs alone for regulated entities in Virginia to switch from fecal to the 1986 criteria. Id.

EPA should take a hard look at Virginia's regulatory cost estimates, which were developed by the Virginia Department of Planning and Budget. Id. These cost estimates should be used, along with any others developed by other states that already adopted EPA's criteria to prepare a more meaningful economic anal

**Response:**

See response to Economic Burden 5 comment code.

Virginia's proposed regulatory notice (November 2001) says, "regarding the advantages and disadvantages to the agency for the bacteria amendments, limited data indicates that using the new bacterial indicators may result in equal to or greater numbers of waters identified as impaired than those identified using the fecal coliform indicator." The State estimated that an additional 102 TMDLs would be necessary over the next 10 years (i.e., 2001 - 2011), based on a preliminary analysis of bacteria data at 100 sites throughout the State. These data indicate that the number of samples exceeding an SSM value of 61 enterococci/100 mL (a much more stringent criteria than required by the rule) is 40% higher than the number of samples exceeding the instantaneous maximum fecal coliform criteria of 1,000 colonies/100 mL.

Under Virginia implementation procedures, in order for a water body to be classified as impaired and require a TMDL, the observations must exceed the criteria more than 10% of the time.

Therefore, just because 40% more observations exceed 61 enterococci/100 mL compared to the fecal coliform criteria, this does not translate into the development of 40% more TMDLs because the stream may already be exceeding the current criteria more than 10% of the time.

Under the State's current implementation procedures (impairment indicated by samples exceeding criteria more than 10% of the time) and the enterococci criteria in the rule (geometric mean of 35/100 mL and SSM value of 104/100 mL), the data indicate that approximately 1% more sites would be impaired for enterococci than for fecal coliform. However, the enterococci criteria would not apply to all 100 of the monitoring sites (*E. coli* criteria applies to all fresh waters and enterococci applies to all marine waters).

Additional information from the State's 2004 draft 305(b)/303(d) Water Quality Assessment Integrated Report indicate that there are no waters listed as impaired for enterococci that are not also listed for fecal coliform, and there are only 4 waters listed as impaired for *E. coli* and not for fecal coliform. Water quality monitoring data from the Virginia Department of Environmental Quality (DEQ) indicate that for two of those *E. coli* impaired waters, fecal coliform values were also above the criteria more than 10% of the time. The other two waters do not have fecal coliform data to indicate whether exceedances exist. Therefore, based on the Virginia DEQ monitoring data and the State's draft 2004 303(d) list, EPA does not believe that bacteria TMDLs would increase due to implementation of the *E. coli* and enterococci criteria.

The State also estimated that monitoring costs would increase by \$3-4 million per year. This estimate is based on sampling costs of about \$160 per sample for *E. coli* and enterococci. Fecal coliform sample costs are estimated to about \$43.50 per sample, about one third of the *E. coli* and enterococci costs. EPA collected fecal coliform, enterococci, and *E. coli* monitoring cost data from several different laboratories throughout the country. EPA found that analytical costs for *E. coli* and enterococci are approximately \$50 per sample. Costs for fecal coliform appear to be about the same as those for *E. coli* and enterococci. Therefore, EPA estimates that the incremental cost associated with monitoring for *E. coli* and enterococci would be negligible.

Experiences from facilities currently meeting the *E. coli* and enterococci criteria, as well as the current fecal coliform criteria, and literature data regarding concentration and inactivation of these bacteria, suggest that chlorination processes can be upgraded or adjusted to produce the levels of bacteria necessary for compliance with the rule. Therefore, switching to nonchlorine based disinfection or adding tertiary filtration prior to disinfection is not necessary.

EPA does not have specific information on the disinfection process (e.g., chlorine dose, volume of contact basin, frequency of maintenance) at the sample facilities. Therefore, EPA used "one size fits all" estimates for process optimization costs. In actuality, facilities may not have to implement all of the modifications for which EPA estimated costs in order to meet limits based on the criteria. Hence, costs are most likely overestimated.

## **Issue: Economic Burden 13**

**Organization Name:** The CSO Partnership

**Document ID:** 197

**Comment ID:** 416

**Comment:**

**Regulatory Flexibility Act Analysis is Incorrect as to the Lack of Impacts on Small Entities and Must Be Redone**

The proposed rule makes the following assertion:

"Today's proposed rule establishes no requirements applicable to small entities, and so is not susceptible to regulatory flexibility analysis as prescribed by the RFA."

This is clearly erroneous. Saying the standards themselves do not apply to any small dischargers is clearly inconsistent with both the letter and spirit of the RFA. This rule will impact hundreds, if not thousands of small communities with POTWs that will now have to meet the new criteria. Moreover, if SSMs/UPVs are imposed, this will be a direct and significant change in the way most of these facilities have been permitted.

Moreover, these new criteria will clearly apply to impaired waters determinations, which impact small communities through storm water requirements. While much of this concern would be ameliorated by a decision to only impose a geometric mean for assessment and NPDES purposes, even the geometric mean will pose a new and substantial impact for many small communities.

If the Virginia analysis predicting 40% more impaired waters and, therefore, 40% more TMDLs is correct, there will be a substantial impact on small entities from that result alone. Again, if Virginia's economic analysis is correct, the additional monitoring costs for every small regulated entity will be considerable.

The proposed rule seeks to defend the finding of no impact by asserting: "EPA's action today does not impose any of these as yet unknown requirements on small entities."

EPA should note that in states like South Carolina, which preclude by regulation mixing zones for bacteria limits in NPDES permits, these standards will directly apply to every small discharger discharging to coastal waters. The same is true for most of the other states, which do not allow mixing zones for NPDES dischargers. There can be no dispute that in most states subject to the rule, the criteria EPA promulgates will directly apply to almost every small discharger in the affected states and jurisdictions. This is absolutely the case with the geometric means - regardless of whether the SSMs/UPVs are imposed.

Of course, if the UPVs are imposed, they will trigger enormous new impacts. A good example of this is the recent TMDLs developed by Indiana and Michigan for the St. Joseph's River. Those TMDLs apply the UPVs at the end-of-pipe for all point source dischargers, including storm water discharges. EPA's position of "no impacts" to small entities is very surprising given how these standards are being imposed in some states, with full EPA review and approval.

That said, one important way to ameliorate the impacts to small communities would be ensure the rule clarifies that only the geometric mean applies for NPDES, attainment, and TMDL purposes.



**Response:**

The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq., generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations and small governmental jurisdictions.

After considering the economic impacts of today's rule on small entities, EPA determined that this action will not have a significant economic impact on a substantial number of small entities. As discussed below, these water quality standards do not directly apply to any discharger, including small entities.

In the "Economic Analysis for Final Water Quality Standards for Coastal Recreation Waters," EPA presents an analysis which supports a conclusion that today's rule will likely affect only a few small entities.

States have flexibility in how NPDES permit limits are established, which includes the allowance of mixing zones where appropriate. Virginia, in particular, places residual chlorine requirements in permits in lieu of monitoring for fecal coliforms, and other States could choose to implement the new criteria in the same manner. EPA's cost analysis for the rule evaluates the potential impacts that may result from State implementation for both large and small NPDES-permitted entities. For the final rule, EPA also conducted a screening analysis of the potential impacts and concluded that the rule will not have a substantial impact on a significant number of small entities.

The implementation guidance also allows States and Territories latitude in determining impairment in waters based on the enterococci and *E. coli* criteria. EPA recommends that the geometric mean be used when there are adequate data, but in the absence of adequate data, that SSMs be used.

EPA provides recommended criteria and guidance on how criteria should be implemented in discharge permits. EPA's oversight and approval relates only to ensuring that States and Territories adopt criteria and procedures that are at least as protective as those recommended by EPA. Should States or Territories choose to adopt more stringent criteria or procedures than EPA recommends, EPA would approve them.

EPA determined that the final rule will not have a significant impact on a substantial number of small entities. (Also see responses to the Economic Burden 1, Economic Burden 5, and Economic Burden 12 comment codes).

## Issue: Economic Burden 14

**Organization Name:** Massachusetts Water Resources Authority

**Document ID:** 245

**Comment ID:** 176

**Comment:**

It is worth noting that EPA has had these proposed criteria on the books for almost 20 years, yet has not approved a method for measuring Enterococcus in wastewater. The focus of Enterococcus as a pathogen indicator has been limited primarily to bathing beaches. It is premature to allow promulgations of new Enterococcus limits for wastewater when little or no background information exists to assist in implementation. Two challenges identified by MWRA are as follows:

In preliminary studies, MWRA has identified differences between Enterococcus methods when analyzing wastewater samples-one method (EPA1600) shows consistently lower counts than the other (SM 9230C) in treated wastewater, and leads MWRA to believe that the EPA1600 method is inappropriate for wastewater analysis. The marked difference between the two methods is particularly worrisome if EPA or States use Enterococcus results analyzed with method EPA 1600 to determine achievable limits in treated wastewater. Enterococcus concentrations in chlorinated wastewater analyzed with method EPA 1600 may be artificially low, and may lead to the false conclusion that meeting proposed EPA limits is achievable in chlorinated wastewater when in fact it is not.

**Organization Name:** Massachusetts Water Resources Authority

**Document ID:** 245

**Comment ID:** 484

**Comment:**

Fundamental methodological issues, implications for wastewater treatment (the ability to meet the proposed limits with existing treatment technology - particularly CSO treatment technologies), and potential environmental effects of altered treatment necessary to meet proposed enterococcus criteria should be thoroughly considered before new pathogen discharge limits are promulgated. Even if effective treatment modifications can be made, EPA has not demonstrated in a compelling way that public health risks are decreased with these new limits, or that guidelines for each bacterial indicator (*E. coli*, enterococcus, or even fecal coliform) are equally indicative of treatment performance and/or water quality.

**Organization Name:** William Hastback

**Document ID:** 157

**Comment ID:** 419

**Comment:**

EPA simply dismisses the additional cost associated with creating a situation in which state agencies and/or permitted wastewater dischargers will have to have both fecal coliform and enterococcus standards and meet both standards so they can satisfy the requirements of both bathing beach and shellfish harvest area water quality standards.

On page 47 of the Review Draft, at the end of section 4.2.1, EPA states that "...wastewater treatment plants chlorinating their effluent **may find enterococci more resistant to chlorination than fecal coliforms or *E. coli*.**" Will that require higher chlorine levels in treated effluent to

destroy the new indicator? Has EPA considered the effects that higher chlorine residuals will have on marine resources such as larval stages of invertebrates and fish? If so, I am unable to find that discussed in the Review Draft.

Many wastewater treatment facilities are considering the switch to UV disinfection methods, specifically to avoid the problems that chlorination creates, particularly in the saltwater environment. Does EPA have any information on how effective UV treatment is in killing enterococcus? Does it require a different UV wave length than is used for coliform bacteria? If so, it seems that WWTPs using UV now would have to install a second UV system to kill enterococcus to meet the new permit requirements that will be adopted someday. That would clearly be a considerable expense, well above and beyond the cost incurred for the additional testing for both fecal coliforms and enterococcus in the effluent that would be required for all WWTPs and other permitted discharge of fecal material, such as CSOs.

**Response:**

Experiences from facilities currently meeting the *E. coli* and enterococci criteria, as well as the current fecal coliform criteria, and literature data regarding concentration and inactivation of these bacteria, suggest that chlorination processes can be upgraded or adjusted to produce the levels of bacteria necessary for compliance with the rule. In its analysis of potential costs, EPA estimated that optimization of existing disinfection processes, including increasing chlorine dose, adding contact basins to increase contact time, and improving mixing conditions, would enable the facilities to comply with the final rule.

The analytical methods for enumerating enterococci have been subjected to interlaboratory validation in an assortment of disinfected wastewaters, including wastewater disinfected by chlorination. Based on the validation study, Method 1600 was characterized with an acceptable overall mean recovery of 90.8% in disinfected wastewater. However, false negative confirmation rates in secondary and disinfected wastewaters prompted a follow-on study that indicated that 81% of atypical pink to red colonies without halos that were >0.5 mm diameter verified as enterococci. As a result, EPA recommends that pink to red colonies without halos that are >0.5 mm in diameter be verified, especially if large numbers of these colonies are observed in a particular matrix.

Increasing chlorine dose for compliance with the new bacteria criteria should not be necessary if other parameters are optimized, such as improving mixing conditions, increasing basin cleaning frequency to prevent build up of organic matter on chlorination tank walls, and increasing contact time so that the chlorine is consumed prior to discharge. If chlorine dose is increased, and the additional improvements listed above do not prevent an increase in residual chlorine concentrations, improvements in dechlorination may also be necessary. However, the cost of such dechlorination improvements (e.g., increasing dechlorination chemical doses) would be relatively minimal compared to chlorination process optimization costs.

Limited available evidence suggests that enterococci are not appreciably different in UV sensitivity than fecal coliform (EPA 811-R-96-002, Exhibit 2-8) in raw sewage. EPA does not expect that a change in UV wave length would be required to treat either enterococci or *E. coli*. EPA is not aware of studies indicating the sensitivity of enterococcus or fecal coliform to different wavelengths in the UV spectrum.

## Issue: Economic Burden 15

**Organization Name:** King County Department of Natural Resources and Parks

**Document ID:** 204

**Comment ID:** 424

**Comment:**

The procedures for enterococcus, including method quality control tests (both MF and MPN) are more complex than for FC, and require a far greater amount of experience to be done accurately. The cost of the membrane filtration method is 2,680% higher than the cost of the FC or *E. coli* tests, based solely on the cost of media ingredients for the new EPA approved procedure.

**Response:**

Procedures for enumerating enterococci are relatively new compared to those for fecal coliform. As more testing is conducted, the difficulty and time required to perform the tests will decrease. Also the rule does not require monitoring. Therefore, the frequency or number of samples taken can be adjusted to account for any increase in analytical costs.

EPA does not have the source of the commenter's estimated costs for the membrane filtration media used to measure enterococci. However, the majority of the analytical costs will most likely be attributable to the labor hours required to perform the procedure and not the testing materials. EPA collected fecal coliform, enterococci, and *E. coli* analytical cost data for both the membrane filtration and most probably number methods from several different laboratories throughout the country. Costs for fecal coliform are comparable to those for *E. coli* and enterococci.

EPA conducted a survey of State, municipal, and commercial laboratories that routinely conduct bacterial analysis of water to compare the incremental analytical costs for existing total and fecal coliform methods already employed by many water quality monitoring programs with the methods proposed here. The mean analytical costs for *E. coli* and enterococci were \$63 (\$50-\$80) and \$64 (\$50 - \$80), respectively. The mean analytical costs for fecal coliforms and *Salmonella* were \$75 (\$60-100) and \$163 (\$100-\$225), respectively.

## Issue: Economic Burden 16

**Organization Name:** King County Department of Natural Resources and Parks

**Document ID:** 204

**Comment ID:** 425

**Comment:**

There are significant implications for the wastewater treatment plant permittees with this switch to enterococcus. There has been a long-standing FC technology standard conventionally accepted by the federal and state government. Has EPA undertaken the work necessary to identify the new technology based standard for enterococcus that will be required for all future permits? This will be a significant lack of guidance if no appropriate tech standard has been developed.

**Response:**

Based on available data (see the Economic Analysis for the rule), EPA believes that current disinfection technologies, when operated properly can achieve permit limits based on the enterococci criteria.

Experiences from facilities currently meeting the *E. coli* and enterococci criteria, as well as the current fecal coliform criteria, and literature data regarding concentration and inactivation of these bacteria, suggest that chlorination processes can be upgraded or adjusted to produce the levels of bacteria necessary for compliance with the rule. Therefore, switching to nonchlorine based disinfection or adding tertiary filtration prior to disinfection is not necessary.

EPA does not have specific information on the disinfection process (e.g., chlorine dose, volume of contact basin, frequency of maintenance) at the sample facilities. Therefore, EPA used "one size fits all" estimates for process optimization costs. In actuality, facilities may not have to implement all of the modifications for which EPA estimated costs in order to meet limits based on the criteria. Hence, costs are most likely overestimated.

## **Issue: Economic Burden 17**

**Organization Name:** Pacific Coast Shellfish Growers

**Document ID:** 164

**Comment ID:** 71

**Comment:**

The new criteria proposed in this Rule will in all likelihood actually result in lower water quality overall, and potentially further degradation and decertification of shellfish growing areas. EPA has failed to adequately assess how the proposed rule, which allows higher bacterial concentrations, will serve to protect this critical designated use.

As an example of the inadequacy of using the enterococci standard: In developing the Total Maximum Daily Load (TMDL) for Grays Harbor, Washington, there was a move afoot to monitor water quality using enterococci instead of fecal coliform. The town of Westport had a fecal-impaired stream (Winter Creek) which flowed into Grays Harbor and over commercial oyster beds. Using the enterococci method, Westport would have met the TMDL standards, but the growing area would have been closed down for failure to meet the NSSP standards for fecal coliform. Grays Harbor has many such short streams, as do other growing areas along the coast, flowing off the land onto shellfish growing areas. These streams are often impaired and a fecal TMDL is the only tool we have to address these problems.

In addition, there are several areas where EPA has failed to adequately demonstrate that the proposed Rule meets all the requisite administrative and legal criteria. The proposed rule fails to take into account the Clean Water Act requirement (Section 303 (c)) to establish standards which will protect all designated uses, including propagation of fish and wildlife and agricultural uses.

**Response:**

This rule does not affect the fecal coliform criteria for shellfish harvesting use designations. It establishes additional water quality criteria to protect recreation. Therefore, States would still be required to develop TMDLs for shellfish harvesting waterbodies impaired for fecal coliform. Waters upstream (or that influence the water quality) of the impaired waterbody would also have to implement any controls necessary to meet the TMDL regardless of that stream's designated use and associated bacteria criteria.

## **Issue: Economic Burden 18**

**Organization Name:** Maryland Association of Municipal Wastewater Agencies

**Document ID:** 201

**Comment ID:** 29

**Comment:**

Finally, because our state does not allow mixing zones for bacteria limits under the NPDES permit program, any standards promulgated by EPA will be applied directly in our members' permits without any consideration of dilution. Thus, there will be a direct impact to our members that should be addressed in the economic analysis. This is especially true if EPA declines to specify that only the monthly geometric mean should be used for permitting purposes.

**Organization Name:** South Carolina Water Quality Association

**Document ID:** 200

**Comment ID:** 19

**Comment:**

Finally, because our state does not allow mixing zones for bacteria limits under the NPDES permit program, any standards promulgated by EPA will be applied directly in our members' permits without any consideration of dilution. Thus, there will be a direct impact to our members that should be addressed in the economic analysis. This is especially true if EPA declines to specify that only the monthly geometric mean should be used for permitting purposes.

**Response:**

In its Economic Analysis, EPA estimated costs for sample facilities, including sample facilities in South Carolina and Maryland, assuming that the enterococci criteria would be applied end-of-pipe (i.e., no dilution), unless site-specific data (e.g., approved variance, 301(h) designation) indicated that dilution would be allowed.

## Issue: Economic Burden 19

**Organization Name:** Hampton Roads Sanitation District

**Document ID:** 220

**Comment ID:** 231

**Comment:**

New York City, the site of the original study experienced significant difficulties with the implementation of the EPA criteria. They have filed a Notice of Intention to repeal the local Health Code based on the original EPA criteria. Moving geometric mean enterococci values calculated from an existing extensive beach monitoring program were cited as the most technically correct method of determining the sanitary status of their beaches. As long as the geometric mean of 35 was maintained, public health would be protected. Any suspiciously high enterococci value beyond the limits of what was routinely observed would trigger sanitary survey which could result in beach closure on the basis of prudent judgment.

Besides the questionable attainability of a SSM bacteriological criteria, another potentially serious impact is that the establishment of a SSM criteria will have substantial and widespread social and economic impact. Once the maximum densities are established, then public officials will be forced to close beaches or sections of beaches when a single sample exceeds the arbitrary meaningless number. It is important for the EPA to promote adoption of reasonably sound standards and avoid unnecessary conservatism in its criteria. Closures will result to avoid litigation rather than to protect the health of swimmers. The needed monitoring has not been conducted to measure how often or when this will occur. Nor has the monitoring been conducted to identify the cause or significance of exceeding single sample standard. Should high numbers or a single high number happen on a holiday weekend the instantaneous impact of public ire will likely be overridden by the long-term negative effects experienced in subsequent years to the resort area.

**Response:**

This rule does not require SSMs as "never-to-exceed" values for Clean Water Act purposes other than beach monitoring. SSMs are values that, with a certain degree of confidence, indicate that a waterbody likely exceeds the geometric mean value. The State can collect additional data on a receiving water if it believes that the violation of the SSM does not indicate violation of the geometric mean.

For purposes of beach monitoring and notification, the concept of comparing single sample results to maximum value is a longstanding one, even with the previous fecal coliform criteria. Today's rule will require the use of a different indicator for some beach monitoring and notification programs, from fecal coliform to enterococci or *E. coli*. However, many States and Territories included in today's rule already include enterococci or *E. coli* maximum values in their health department requirements. Thus, they are already generally accepted by public health officials as appropriate for determining day-to-day quality at beaches.



## **Issue: Economic Burden 20**

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 381

**Comment:**

An issue that is not assessed realistically in the draft regulation is that by allowing higher bacterial concentrations in swimming areas there will be higher concentrations in neighboring shellfish areas. Though on paper the criteria will be in the right place and providing protection, it seems likely that more decertification and degradation of shellfish areas will result if marine criteria are allowed to be higher in waters that flow through shellfish areas. The EPA draft rule should consider the economic impact of the dual monitoring and analysis that will be required of state and local jurisdictions and industries as a result of this federal rule's applicability to shellfish waters where fecal coliform criteria will still be in place. It should also be acknowledged, even though it cannot be quantified, that there is an increased risk to recreational and commercial shellfish harvesting.

**Organization Name:** William Hastback

**Document ID:** 157

**Comment ID:** 420

**Comment:**

In keeping with its indefensible failure to produce any new data based on recent studies which might have reliable results backed up with clinical data from individuals reporting illness after swimming, EPA has not offered any data that show a relation between enterococcus levels and fecal coliform levels that would be of any use to programs responsible for classifying shellfish harvest areas which in many cases include bathing beach areas.

**Response:**

See response to the Economic Burden 1 comment code.

EPA does not believe that the rule will lead to higher shellfish risks because current implementation procedures for NPDES and TMDLs require that all water quality standards must be met. Thus, changing recreational criteria in adjacent waters does not allow increased discharges if those discharges impinge upon the shellfish areas.

## **Issue: Economic Burden 21**

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 351

**Comment:**

The costs of monitoring for multiple indicators needs to be considered.

**Response:**

See the response to the Economic Burden 1 and Economic Burden 20 comment codes.

## **Issue: Economic Burden 22**

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 386

**Comment:**

The substantial increase in sampling and analytical costs will surely mean a reduction in the frequency of monitoring wherever the law allows or a reduction in the variety of environmental parameters measured - thus further undisclosed detrimental effects of changing indicators are likely. These analytical costs combined with the lost workdays, lost wages, and associated health care costs from the increased number of illnesses that would accompany using the EPA recommended criteria, need to be fully considered by EPA in their proposed rule. Washington's decision to use low-level fecal coliform concentrations has created criteria that are both more protective and far less costly to the state and its cooperators. It is not reasonable for EPA to impose a federal rule that will reduce water quality protection, and increase the economic and social costs to our state. We strongly urge EPA to consider the data and arguments we have provided and remove our state from the federal rule.

**Response:**

See the responses to the Economic Burden 1, Economic Burden 9, and Economic Burden 20 comment codes.

For the reasons described in the response to the Washington comment code, EPA has determined the Washington's fecal coliform criterion of 14/100 is as protective of human health as EPA's 1986 bacteria criteria.

## **Issue: Economic Burden 23**

**Organization Name:** The CSO Partnership

**Document ID:** 197

**Comment ID:** 423

**Comment:**

**EPA's List of Potentially Impacted Parties is Incomplete**

We believe the list of potentially impacted parties should expressly include all communities with combined or sanitary sewer overflows as well as all urbanized areas with storm water runoff. All of these sources will be directly and significantly impacted by the new bacteria criteria.

**Response:**

EPA has revised its list of potentially impacted parties to include these sources (see preamble to the rule). See response to Comment ID 189.

## **Issue: Economic Burden 24**

**Organization Name:** Massachusetts Water Resources Authority

**Document ID:** 245

**Comment ID:** 175

**Comment:**

Inclusion of a SSM for enterococcus in a NPDES discharge permit is unrealistic, and in some cases may be unachievable. Because bacteria increase geometrically, small variations in flow, hypochlorite dosing, and chlorine demand result in highly variable bacteria counts. This is especially true at CSO facilities, which have extreme variations in flows and loads over short time periods. If a SSM were to be incorporated into a permit, dischargers using sodium hypochlorite to disinfect would have to chlorinate more heavily to ensure that this more restrictive limit was met. Increased chlorination results in the formation of more chlorination by-products, would increase toxicity to marine organisms, and would increase treatment cost with arguably little environmental benefit-and possibly increased environmental harm. Even with treatment modifications (namely, increasing hypochlorite dosage) it could not be guaranteed that a single sample maximum limit would be met at all times.

Even with a five year grace period following a new or modified permit, MWRA questions whether best available control technology for CSO treatment will be sufficient to meet a SSM limit for enterococcus. To MWRA's knowledge, there has been little study of enterococcus in wastewater or its treatment using different treatment technologies. To date, MWRA has spent \$3.5 billion for treatment upgrades at its Deer Island WWTP and is planning to spend \$700 million for CSO control. Despite this significant investment, MWRA will not currently meet the most stringent SSM or the geometric mean enterococcus at its WWTP or at its CSO facilities if they were to be incorporated into permit limits.

**Response:**

This comment apparently assumes that criteria would need to be met at end-of-pipe, but this is not a requirement of this rule nor of NPDES regulations. Available data from the MWRA web site indicates that the facility's receiving water (i.e., the Boston Harbor) have enterococci concentrations below the 35 enterococci/100 mL geometric mean criterion. EPA questions the basis of the statement that MWRA would not achieve the enterococci geometric mean criteria. With respect to the single sample maximum component of the criterion, section IV.B.3. of the preamble discusses the flexibility that permitting authorities have with respect to using the single sample maximum.

## **Issue: Effective Date**

**Organization Name:** Michael Doran Techknowledge

**Document ID:** 209

**Comment ID:** 152

**Comment:**

Lastly, since the State of Wisconsin is working diligently to develop water quality standards for bacteria, and related policy, with the intent that such rules and policy be in place during the first half of 2005, it is requested that EPA delay finalization and implementation of this rule until July 2005. This will allow Wisconsin to develop and implement rules and policy that are consistent with EPA criteria, but which make sense locally and can be applied to all waters of the state (not just the Great Lakes waters).

**Organization Name:** Mississippi Department of Environmental Quality

**Document ID:** 207

**Comment ID:** 103

**Comment:**

We are also requesting that EPA allow the states to implement the rule 90 days from the date it becomes final. This will allow us time to interpret our beach usage data and make the appropriate changes to our standards.

**Response:**

See the preamble to today's rule, in particular section VI.D., Effective Date.

## **Issue: Extension Requests**

**Organization Name:** King County Department of Natural Resources and Parks

**Document ID:** 158

**Comment ID:** 456

**Comment:**

With this email I am requesting that EPA extension the comment period for of July 9, 2004 WATER QUALITY STANDARDS FOR COASTAL AND GREAT LAKES RECREATION WATER, PROPOSED RULE from the current August 9th deadline to September 13, 2004 (one additional month plus one week due to Labor Day falling on September 6th). This extension is imperative if full and complete comments are expected by EPA on this critical proposal.

**Organization Name:** King County Department of Natural Resources and Parks

**Document ID:** 158

**Comment ID:** 457

**Comment:**

Considering the appropriate indicator for freshwater will require a wholly different set of comments and thus this also increase the amount of time necessary to prepare complete and useful comment for EPA.

**Organization Name:** King County Department of Natural Resources and Parks

**Document ID:** 158

**Comment ID:** 458

**Comment:**

Thus there are significant issues, in number and complexity, in this proposed rule that requires that EPA give more than merely a month for public comment. I urge you to grant my request and give at least another month of time for us all to comment on this sweeping proposal.

**Response:**

EPA appreciates the comments requesting an extension of the public comment period, but denies the request. In order to comply with Clean Water Act requirements EPA must promptly propose standards for States and Territories that have not promulgated criteria as protective of human health as the 1986 bacteria criteria by April 2004, and must promulgate a final rule 90 days after proposal. See CWA sections 303(i)(3) and 303(c)(4).

EPA recognizes the complexity of issues involved in the implementation of bacteria criteria and looks forward to working with States and Territories as they implement the Federal Criteria and adopt their own criteria in the future.

## **Issue: Fecal Coliform and Compliance with 303(i)**

**Organization Name:** American Forest and Paper Association

**Document ID:** 191

**Comment ID:** 192

**Comment:**

The rule should recognize that the proposed methods, as well as the traditional (e.g. fecal coliform) measurements, simply serve as indicators of the presence of pathogens. If a state can demonstrate the same level of protectiveness with a chosen (e.g. traditional) indicator and standard as one EPA proposes, the State should be able to use it. This is particularly important when a traditional indicator and a standard structured to utilize that indicator has been demonstrated to be as protective as those EPA proposes, and it is lower cost and easier to implement.

**Organization Name:** King County Department of Natural Resources and Parks

**Document ID:** 204

**Comment ID:** 331

**Comment:**

The FC test is a simple, straightforward test accessible to all government and nongovernmental (e.g. volunteer monitoring groups) monitoring efforts. Laboratory personnel are familiar with performing the FC assays using both Membrane Filtration (MF) and Most Probable Number (MPN) methodologies after many years of experience, both being easy to perform, relatively inexpensive, and with data interpretation methods that are well understood. *E. coli* is the next best parameter to test because it correlates well with sewage pollution as evidenced by the epidemiological studies, and because it has a kindred relationship with FC. Thus local health departments and treatment plants will have a familiarity with data interpretation. Such simplicity and transferability of data interpretation will not exist if enterococcus becomes the monitoring parameter.

**Organization Name:** King County Department of Natural Resources and Parks

**Document ID:** 204

**Comment ID:** 335

**Comment:**

Given that enterococci have a longer survival time in the environment than *E. coli* and FC, what is the anticipated impact on the average length of time that a swimming beach would remain closed compared to using an *E. coli* or FC standard? What guidance can EPA provide relating to what the closure period should be?

**Organization Name:** State of Alaska Department of Environmental Conservation/Division of Water

**Document ID:** 175

**Comment ID:** 153

**Comment:**

**Background and Context for These Comments**

We point out that Alaska's current criterion for contact recreation in coastal waters is more stringent by a factor of two than current EPA guidelines. Alaska's current criterion is 100 fecal



colonies per 100 milliliters (ml) as a geometric mean. EPA's 1976 guidelines suggested a criterion of 200 fecal colonies per 100 ml. While EPA's 1986 guidelines changed indicators, it did not change the level of allowable risk.

On the other hand, we understand that relatively recent data suggest that fecal coliform is not a reliable indicator of human illness risk from contact recreation and that the effect of the BEACH Act of 2000, along with EPA's 1986 guidance, is to require that water quality criteria for protection of contact recreation in marine waters use the pathogen indicator enterococci. Alaska is included in the proposed rule because of the requirement to use the enterococci indicator, not because its water quality criterion is not sufficiently protective. We have previously informed EPA that the State of Alaska is in the process of proposing revised bacteria criteria for contact recreation in coastal recreation waters based on the enterococci indicator.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 360

**Comment:**

Washington urges EPA to look beyond just the type of indicator that is specified in state standards when considering whether a state is being as protective as the federal criteria. In determining if a state has criteria that are equally protective, EPA should assess the criteria values chosen by a state in comparison with uncertainty surrounding the federal guidance. This is particularly true in the case of examining the criteria adopted by the state of Washington where almost every individual sample (>99%) where fecal coliform was below 14/100, also had enterococci concentrations below 35/100 ml. This would mean the likelihood that a geometric mean for enterococci would be greater than 35/100 when the geometric mean for fecal coliform was less than 14/100 would be even more remote. In comparison, EPA has allowed significantly greater risk of exceeding the geometric mean of 35/100 mL in its single sample maximum value recommendations.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 486

**Comment:**

Similarly, EPA must not simply assume that any concentration of an alternative indicator is not protective in a state's standards. As alternative indicator criteria become more stringent they become more protective, regardless of how well they perform in predicting the rate of illness. A state that regularly monitors, or one that takes multiple measurements on a regular basis and applies the geometric mean over short windows of time, is more protective than one that rarely if ever collects enough data to calculate a geometric mean or that averages samples across long expanses of time. EPA must keep in mind that the risk of illness is not related to the concentration of pollutants that occurred in the month before or after a family went to the beach -in spite of EPA finding a higher statistical correlation based on seasonal averaging.

**Response:**

EPA recognizes that if a State can demonstrate the same level of protectiveness between its chosen indicator and EPA's criteria, that EPA could consider the State's criterion to be as protective of human health as EPA's criterion. EPA has done so in the rule with regards to the State of Washington. The Washington Department of Ecology provided EPA with paired samples of enterococci and fecal coliform from many locations in part of the Puget Sound. The

Washington Department of Ecology submitted these data as evidence that the Washington fecal coliform criterion of 14 counts/100 ml is as protective of human health as EPA's 1986 enterococci criterion. Section V.A.1 of the preamble to the final rule provides EPA's reasons why it agrees with the Washington Department of Ecology that Washington's fecal coliform criterion of 14/100ml is as protective of human health as EPA's 1986 bacteria criteria in Washington's coastal recreation waters.

EPA does not consider less laboratory familiarity as a factor related to whether a State's current water quality criterion is as protective of health as EPA's criterion. CWA section 303(i)(2)(A) lays out the only situation in which EPA would not promulgate the 1986 enterococci criterion for a State, and that is when EPA determines that the State's current water quality standards are as protective of human health as EPA's 1986 criterion. EPA recognizes that laboratories currently have familiarity with the fecal coliform analytical method and not as much experience with the enterococci analytical method. EPA does not find it unusual for this situation to occur when a newer analytical method or becomes available or water quality criterion changes. The commenter did not provide information showing that laboratories could not conduct the enterococci analytical method; therefore, EPA does not consider this lack of familiarity to be sufficient to preclude requiring a State to adopt the enterococci criterion.

EPA does not have information related to any difference in the length of time of a beach closure based on enterococci versus fecal coliform. EPA's guidance on when a State should reopen a beach is found in National Beach Guidance and Required Performance Criteria for Grants, EPA-823-B-02-004, June 2002, and says "[A]n advisory should not be lifted without sample results showing that the applicable water quality standards have been met."

EPA addresses the comment about the State of Alaska's current fecal coliform criterion in section V.A.1. of the preamble.

## Issue: Federal Register

**Organization Name:** Massachusetts Department of Environmental Protection

**Document ID:** 208

**Comment ID:** 59

**Comment:**

The Department of Environmental Protection submits the following comments on EPA's proposal to establish water quality criteria for bacteria for coastal recreation waters within Massachusetts. As EPA has acknowledged in its Federal Register Notice of July 9, 2004, Massachusetts is in the process of proposing revisions to the Massachusetts Surface Water Quality Standards, 314 CMR 4.00, to reflect EPA's bacteria criteria. Our draft, revised Standards currently are undergoing their final phase of internal review. Additionally, consistent with EPA's recommended bacteria criteria, the Massachusetts Department of Public Health already has incorporated into its public health regulations, which are applicable to bathing beach waters, standards for enterococci and *E. coli*. Massachusetts' current regulations are protective of public health and we anticipate that our Surface Water Quality Standards soon will be consistent with EPA's recommended bacteria criteria as well. In the meantime, therefore, we are of the view that EPA should defer to the state's regulatory processes on this matter. Should EPA proceed toward final rulemaking, given that EPA's proposal sets out various options and approaches, EPA should provide an additional comment period on its proposed final language.

**Organization Name:** Pennsylvania Department of Environmental Protection

**Document ID:** 233

**Comment ID:** 280

**Comment:**

The following are more specific edits and/or corrections that we suggest you consider during the development of final rulemaking:

- Pg 41722 & 41723 - the parenthetical in the following phrase...*single measurements will result in a less cautious (i.e., less protective) decision...* should be (i.e., *with less confidence*) because it does not necessarily mean there will be less protection.
- Pg 41723 - ...*exposure in a given area, a higher degree of protectiveness (i.e., a lower bar for determining an exceedance) is...* should refer to ...*a higher degree of confidence...*
- Pg 41723 - Footnotes 4 and 5 to TABLE 1 - CRITERIA FOR INDICATORS FOR BACTERIOLOGICAL DENSITIES are not referenced in the Table itself. We suspect that these footnotes were probably supposed to be attached to the column headers for the "Single sample maximum allowable density" based on the context of the footnote.

**Organization Name:** South Carolina Department of Health and Environmental Control Bureau of Water

**Document ID:** 161

**Comment ID:** 279

**Comment:**

**Issue:** Why is the scope and depth of the rulemaking so much larger than Section 303(i) requires and from what EPA previously stated to be their intent to publish?

Instead of being a proposed rulemaking that directly specifies the applicable criterion, the states to whom the rulemaking applies, and request for comments on these very specific issues, this notice reads more like an advance notice of proposed rulemaking. There are more questions being asked from EPA requesting additional comments, including previously unreferenced issues, instead of a notice of clear statement and intent with regard to EPA's "final" action on the BEACH Act. Further, considering that all of the comments that the EPA has already received on the issues of the BEACH Act and its implementation have not been completely answered or addressed by the EPA, it appears odd that the EPA would request even more comments on an even greater number of issues.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 445

**Comment:**

Even if Washington is removed from the federal regulation, we request that EPA consider the comments that we are submitting today as well as the comments and materials that we have previously submitted. To begin with, we believe that it is not appropriate to include so many broadly opposing alternatives to the issues contained in a draft rule. This makes the rule difficult to assess since EPA seems ready to take completely opposite approaches on key implementation issues. When an agency is totally up in the air on what it thinks is the right overall direction, we would suggest that it is not really ready to develop a regulation.

**Response:**

EPA thanks commenters for editorial comments on the preamble to the proposal. Footnotes 4 and 5 to Table 1 of today's rule are now referenced in the "Single sample maximum allowable density" column.

EPA disagrees that the alternatives proposed take completely opposite approaches and thus make it difficult to assess the proposal. EPA presented a range of options that it considered and discussed those options in detail in the proposal in order to generate comment from the public on the options. Since the BEACH Act requirements are predicated on the 1986 bacteria criteria, and there could be several ways to interpret the 1986 document, EPA felt it was prudent to request public comment on these issues.

Because today's rule differs little from the proposed rule, EPA determined it was not necessary to repropose any portion of the proposal.

EPA recognizes that some states regulate public bathing beaches through their Department of Health requirements, which are consistent with EPA's recommended water quality criteria for bacteria. However, these requirements are not necessarily water quality standards, as defined by CWA section 303(c). Section 303(i) of the Clean Water Act is clear that states must adopt criteria into their water quality standards for coastal recreational waters that are as protective of human health as the EPA 1986 bacteria criteria. EPA also recognizes that some States and Territories are in the process of adopting water quality standards to be as protective of human health as EPA's 1986 bacteria criteria. Once a State or Territory submits the adopted Standards to EPA, the Agency will use CWA sections 303(c) and 303(i) to guide its review of the standards. Water quality standards do not become effective for Clean Water Act purposes until EPA approves them (40 CFR 131.21). Once EPA approves a State's or Territory's standards as being as protective of human health as EPA's 1986 bacteria criteria, those will become the applicable water quality

standards even before EPA undergoes rulemaking to remove that State or Territory from 40 CFR 131.41.

## **Issue: Florida**

**Organization Name:** Florida Department of Environmental Protection

**Document ID:** 229

**Comment ID:** 79

### **Comment:**

EPA's characterization of Florida's status regarding adoption of the 1986 water quality criteria for coastal recreation waters is correct. We have held two public workshops to acquaint the public with the issue and plan to propose adoption of the enterococci geometric mean for coastal recreation waters.

### **Response:**

EPA thanks the commenter for providing information on progress toward full compliance with the BEACH Act requirements.

## **Issue: General Agreements and Disagreements**

**Organization Name:** American Shore and Beach Preservation Association

**Document ID:** 159

**Comment ID:** 136

**Comment:**

The American Shore and Beach Preservation Association (ASPBA) strongly supports the proposed EPA regulation to improve standards for water quality monitoring at our Nation's beaches.

Each of us is keenly aware that the millions of Americans and foreign tourists who use America's beaches have a right to swim and play in water that meets realistic, yet stringent, health standards. All of us know the consequences when beach water is polluted. Lost beach visitor days bring disappointment to all those who want to enjoy our Nation's beaches. They also translate into lost dollars for local businesses, as well as lost tax revenues at the regional, state, and national levels.

The ASBPA wants to work with your agency to lessen the causes of beach water pollution. This important task can be achieved over time through our combined efforts and resources. In the interim, improved monitoring standards are a critical first step to protect the public's health and safety.

**Organization Name:** American Society for Microbiology

**Document ID:** 162

**Comment ID:** 37

**Comment:**

The ASM applauds the EPA for developing standards that protect human health from exposure to microbial pathogens and potential pathogens while using marine and non-marine waters for recreation. The ASM recognizes that the proposed rule is intended to promote public health by establishing levels of microbial contamination that do not result in unacceptable risks for illness. The ASM further recognizes that the proposed rule would apply to States and Territories that do not have in place standards that comply with the requirements of section 303(i) of the Clean Water Act of 1986.

**Organization Name:** Jeffrey A. MacDonald

**Document ID:** 177

**Comment ID:** 477

**Comment:**

As there is currently an array of different bacteriological indicators being used by various states for NPDES, beach, and other environmental monitoring, a move toward standardization of the regulatory tool used to gauge pollutional status is considered a positive step.

**Response:**

EPA thanks commenters for their support. EPA also believes that the promulgated criteria are an important step to protect public health and safety at our nation's beaches.

EPA acknowledges the comment supporting standardization of the regulatory tool used to gauge pollutional status. Today's rule takes a step towards that end by promulgating criteria for pathogens and pathogen indicators based on EPA's 1986 bacteria criteria document for States and

Territories that have not yet adopted criteria as protective of human health as the 1986 bacteria criteria document.



**Issue: General Concerns 1**

Comments originally listed under this issue have been reassigned to another issue.

**Issue: General Concerns 2**

Comments originally listed under this issue have been reassigned to another issue.

### **Issue: General Concerns 3**

Comments originally listed under this issue have been reassigned to another issue.

## **Issue: General Concerns 4**

**Organization Name:** King County Department of Natural Resources and Parks

**Document ID:** 204

**Comment ID:** 327

**Comment:**

While we understand that the BEACH Act of 2002 included some important mandates regarding assurance that all primary contact recreational activities throughout the country be protected, we are concerned that this "one size fits all" rulemaking will create significant confusion and additional costs to permittees, without increasing protection.

**Response:**

As stated in the preamble to the rule, EPA is fulfilling its obligations under section 303(i)(2)(A) of the Clean Water Act to "promptly propose regulations for the State setting forth revised or new water quality standards for pathogens and pathogen indicators described in [section 303(i)(1)(A)] for coastal recreation waters of the State." EPA has included provisions in the rule to allow States and Territories, consistent with the Clean Water Act and implementing regulations, to exercise some flexibility in how they implement the criteria. For example, the rule allows States and Territories to compute site-specific single sample maximums based on site-specific data. The preamble to the rule describes other areas of flexibility that the State or Territory can use to exercise flexibility such that the rule is not a "one size fits all" rule.

## Issue: General Concerns 5

**Organization Name:** Municipal Environmental Group

**Document ID:** 225

**Comment ID:** 82

**Comment:**

It is frustrating and counterproductive to have that effort compromised by federal action that creates a one-size-fits-all approach to regulating bacteria levels nationwide. Such an approach is very costly to taxpayers because it fails to account for the area-specific needs of the subject waterbodies.

This process will also erode the state's ability to develop well-planned state criteria with the advent of federal criteria hanging over the state. We know from our personal experience on other state water advisory committees that it takes considerable time and effort to undertake detailed analyses of issues and measured consideration of competing interests that are required to develop protective and reasonable standards. The state bacteria committee has been attempting to undertake such a process but has been severely constrained by the federal pressures surrounding the committee. It is certainly not in the public interest to quickly develop poor state standards instead of taking the additional time necessary to develop good standards based on sound and thorough analysis.

Nor are the standards needed immediately to protect public health since point sources already protect against bacteria risks through the states' disinfection policy and the disinfection requirements in WPDES permits.

**Organization Name:** Municipal Environmental Group

**Document ID:** 225

**Comment ID:** 83

**Comment:**

For these reasons, MEG urges EPA to reconsider and withdraw its effort to develop federal bacteria criteria or at least to withdraw the intended application of those criteria to Wisconsin. We appreciate the opportunity to participate in the rule development process and to submit these comments. Should you have any questions, please feel free to contact us.

**Response:**

As stated in the preamble to the rule, EPA is fulfilling its obligations under section 303(i)(2)(A) of the Clean Water Act to "promptly propose regulations for the State setting forth revised or new water quality standards for pathogens and pathogen indicators described in [section 303(i)(1)(A)] for coastal recreation waters of the State." EPA has included provisions in the rule to allow States and Territories, consistent with the Clean Water Act and implementing regulations, to exercise some flexibility in how they implement the criteria. For example, the rule allows States and Territories to compute site-specific single sample maximums based on site-specific data. The preamble to the rule describes other areas of flexibility that the State or Territory can use to exercise flexibility such that the rule is not a "one size fits all" rule.

**Issue: General Concerns 6**

Comments originally listed under this issue have been reassigned to another issue.

## **Issue: General Concerns 7**

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 355

**Comment:**

Greater public health gains would occur from education and sanitation facilities.

**Response:**

EPA acknowledges that public health gains would occur from education and sanitation facilities. As stated in the preamble to the rule, EPA is fulfilling its obligations under section 303(i)(2)(A) of the Clean Water Act to "...promptly propose regulations for the State setting forth revised or new water quality standards for pathogens and pathogen indicators described in [section 303(i)(1)(A)] for coastal recreation waters of the State."

## Issue: Hawaii

**Organization Name:** Department of Environmental Services City and County of Honolulu

**Document ID:** 235

**Comment ID:** 292

**Comment:**

The EPA has determined that the State of Hawaii Water Quality Standards (WQS) do not satisfy BEACH Act requirements and is therefore proposing to apply the 35 cfu/100 ml enterococcus geometric mean and single sample maximum criteria to Open Coastal Waters, i.e. marine waters up to 600 feet deep. We firmly believe that these criteria should not be applied to the entire Open Coastal Waters zone because "swimming, bathing, surfing or similar water contact activities" do not take place up to the 600-foot depth. Section 11-54-08(b) of the WQS already specifies an enterococcus GM standard for marine recreational waters within 1000 feet of shoreline. We feel that the determination of the appropriate primary contact activity zone should be left up to DOH, who has primacy on water quality standards for the State of Hawaii.

**Organization Name:** Department of Environmental Services City and County of Honolulu

**Document ID:** 235

**Comment ID:** 296

**Comment:**

*Application of EPA Marine WQ Bacterial Criteria to Hawaii Open Coastal Waters*

On p. 41732 of the July 9, 2004 Proposed Rules, EPA is including Hawaii in the rulemaking because there are no numeric criteria protecting State waters beyond 300 meters from shore, although these waters are designated for recreation in the State's water quality standards. Further, on p. 41742, Sections 131.41(e)(2) and (3) propose to essentially apply marine waters criteria to Hawaii Open Coastal Waters. We feel that applying the marine waters criteria to the entire Open Coastal Waters zone, i.e. shoreline to 600-foot depth, is not in keeping with the BEACH Act of 2000 for the following reasons:

1. In Section 5 of the BEACH Act the term "Coastal Recreation Waters" includes:

"(i) the Great Lakes and (ii) marine coastal waters (including coastal estuaries) that are designated under section 303(c) by a State for use for swimming, bathing, surfing, or similar activities."

Primary contact activities such as swimming, bathing, surfing, do not occur in areas of 600-foot depth on Oahu, which lies over 1.5 miles offshore.

2. Section 11-54-03 (c)(2) of the Hawaii Water Quality Standards (WQS) states:

"It is the objective of class A waters that their use for recreational purposes and aesthetic enjoyment be protected."

This applies to the Class A waters of the Open Coastal Waters zone (shoreline to 600-foot depth).

There is no definition of "recreational purposes" in the WQS. It appears recreational purposes in this section of the WQS is not limited to just primary contact activities but any full contact or incidental contact recreational activity in Class A waters. Primary contact activities do not occur



out to 600-foot depths. There may be incidental contact, which these proposed regulations are not addressing.

Another reason why we feel that recreational purposes in this section of the WQS is not limited to only primary contact activities is that the WQS also specifies recreational use for deeper Class A Oceanic Waters. Oceanic waters means "all other marine waters outside of the 183 meter (600 feet or 100 fathom) depth contour". It appears that the intent is to protect deep ocean recreation e.g. sailing, and recreational purposes in the WQS covers general marine recreation. Of course, it would be even more unlikely that primary contact activities would occur in waters outside of the 600-foot depth.

3. We believe that the intent of Section 11-4-8(b) Specific criteria for recreational areas of the Hawaii WQS is to protect the public health of recreational beach users as required by the BEACH Act. The shoreline to 300-meter from shore area is generally where primary contact activities occur, however a recreational survey would be in order to better determine where primary contact activities take place. Further, the existing enterococcus geometric mean limit of 7 c.f.u./100ml is the same type of limit found in the 1986 Ambient Water Quality Criteria for Bacteria. When the State DOH adopted the 7 c.f.u./100 ml standard, they followed the 1986 document and used an illness rate of 10 per 1,000 swimmers instead of the 19, which correlated to geometric mean limit of 35 c.f.u./100 ml. We feel that the 7cfu/100 ml GM standard is overly restrictive and support EPA's proposal to apply the 35 cfu/100 ml GM standard to the shoreline to 300 meter area.

We recommend that the State Department of Health, City and County of Honolulu and other affected counties conduct a statewide recreational survey to determine where primary contact activities occur and where the 35 cfu/100 ml GM limit should apply. BEACH funds could be used to fund the survey. Until such time it is determined how far out from shoreline primary contact activities do occur, the EPA should not apply the 35 cfu/100 ml criterion for waters outside of 300 meters from shore.

**Organization Name:** State of Hawaii Department of Health/Environmental Health Administration

**Document ID:** 195

**Comment ID:** 394

**Comment:**

**Waters to be Covered:** The State prefers to retain the 300 meter/1000-ft boundary in the State's current rule, demarcating the more frequently used near shore open coastal recreational waters from less-frequently used open coastal and oceanic waters further offshore. While Hawaii's rules designate recreation as a use for class A marine waters, and those waters extend three miles from shore, HAR section 11-54-8(b) designates the 300 meters/1000 feet from shore as "marine recreational waters" and only that section sets indicator bacteria limits for marine waters. Section 11-54-8(b) will retain that distinction in our proposed state amendment. DOH has not so far seen a need to adopt bacterial water quality standards for waters beyond 300 meters/1000 feet from shore.

In any event, this is an issue of importance. The City and County of Honolulu challenges whether there is actual full body contact use of waters more than 1000 feet from shore and sees a multi-million dollar cost to implement the proposed federal rules. Without taking a position on the City's concerns, DOH believes that the State should retain the ultimate authority to determine the extent of the waters covered by indicator bacteria standards, consistent with federal law, and be able to address the issue through rule making and public participation procedures here in Hawaii.

**Response:**

For information on specific States and Territories, see the preamble to today's rule, in particular section V.B., Which States and Territories are Included in Today's Rule?

This final rule applies to coastal recreation waters, as discussed in the preamble to today's rule, in particular section IV.A., Application of the Rule to Coastal Recreation Waters. Today's rule does not designate uses but rather establishes criteria for marine waters designated by Hawaii for swimming, bathing, surfing, or similar water contact activities. Section 11-54-03(c)(2) of the Hawaii water quality standards defines the objectives [designated uses] of Class A ocean waters to be for "recreational purposes", as noted by the commenter. However, the same part of the Hawaii water quality standards goes on to speak about "recreation in and on these waters." Therefore, EPA interprets Hawaii's water quality standards to designate Class A ocean waters for swimming, bathing, surfing, or similar water contact activities. If the State believes that primary contact recreation does not occur in certain waters that State could conduct a use attainability analysis consistent with 40 CFR 131.10(g) to remove the use.

EPA thanks the commenters who provided information on progress toward full compliance with the BEACH Act requirements.

## Issue: Implementation Guidance

**Organization Name:** Association of Metropolitan Sewerage Agencies

**Document ID:** 227

**Comment ID:** 283

**Comment:**

*Lack of Guidance and EPA-Approved Test Methods Hamper Implementation*

The lack of implementation guidance for the 1986 criteria and EPA-approved test methods for enumerating *E. coli* and enterococci are two reasons why many states have yet to adopt the 1986 criteria. Until these issues are fully resolved, they will continue to affect implementation of the proposed criteria.

*Implementation Guidance*

Drafts of the implementation guidance were released in May of 2002 and November 2003. EPA indicated that the guidance might be finalized in Spring 2004. EPA, however, has now informed stakeholders that the guidance may never be finalized. Even more troubling is the fact that key components of the guidance have been rolled into the proposed rule, which will likely only result in providing less flexibility to states in how they implement the standards.

**Organization Name:** New York State Department of Environmental Conservation

**Document ID:** 218

**Comment ID:** 87

**Comment:**

Unaddressed Issues Regarding Implementation Guidance.

In order to fully incorporate the federal standards into New York's water program, it is essential that the USEPA complete and issue its final Implementation Guidance for Ambient Water Quality Criteria for Bacteria. We ask that this final guidance address the issues and concerns that have been repeatedly raised in past comments from New York, and be issued by the effective date of the final rule.

**Organization Name:** Pennsylvania Department of Environmental Protection

**Document ID:** 233

**Comment ID:** 246

**Comment:**

While on the surface, the proposal appears to offer flexibility; the final regulation will greatly limit state-specific considerations by setting many implementation issues in the regulation itself. Such incorporation of implementation is contrary to most rulemakings, which usually do not contain the specifics of implementation.

The myriad options for implementation listed in the proposal have been under discussion between EPA and the states (through the Association of State and Interstate Water Pollution Control Administrators or ASIWPCA) for over two years. These issues were to be addressed in the Bacteria Implementation GUIDANCE. The final regulation will place final answers to these issues in regulation. We do not support replacing the almost completed guidance with regulatory provisions relating to these issues.

**Organization Name:** Pennsylvania Department of Environmental Protection

**Document ID:** 233

**Comment ID:** 249

**Comment:**

PA DEP is concerned with EPA's decision to abandon its development of detailed scientific and policy guidance (*Implementation Guidance for Ambient Water Quality Criteria for Bacteria*, May 2002 Draft, EPA-823-B-02-003) concerning adoption and implementation of EPA's 1986 recommended water quality criteria for bacteria. We believe this effort, which engaged many state representatives, ASIWPCA, and EPA staff, was quite useful in addressing the specific concerns of the states as they proceed with adopting, and eventually to aid the states in implementing, these criteria. We are concerned, however, that if the EPA does not complete this task, but decides to roll the key issues of that draft implementation guidance into the current rulemaking, that states will lose flexibility and their discretion on how the criteria are to be implemented, especially as it pertains to other waters that do not immediately fall under the scope of the BEACH Act and coastal recreational waters. So, we encourage EPA to resume this undertaking with the states and ASIWPCA to finalize this much needed implementation guidance for the bacteria criteria.

**Response:**

The requirements of the BEACH Act effectively limit the flexibilities for coastal recreation waters that the draft Implementation Guidance for Ambient Water Quality Criteria for Bacteria originally envisioned for waters to which the bacteria criteria would apply. However, States with inland waters can choose from a variety of options for protection of recreation uses with respect to bacteria for those waters.

EPA is only promulgating criteria that are as protective of human health as the 1986 bacteria criteria, as required by the BEACH Act. EPA has not promulgated implementation procedures with today's rule, but has illustrated approaches that States may use when implementing the criteria. In illustrating these approaches, EPA has attempted to provide information on key issues that the Agency also addressed in the draft implementation guidance. EPA intends to continue work on finalizing the Implementation Guidance to address those issues not contained in today's rule.

However, EPA notes that the implementation problems associated with the 1986 bacteria criteria are not unique to those criteria. Those problems are inherent to indicator bacteria, and already existed with the previous fecal coliform criteria, as well.

## **Issue: Intrastate vs Interstate Basis**

**Organization Name:** Buckeye Florida

**Document ID:** 172

**Comment ID:** 239

**Comment:**

*Intrastate vs. Interstate Determinations of Use Intensity* - Again, the use of the geometric mean only for the water quality criteria will preclude the requirement for EPA to specify this.

**Organization Name:** County of Orange, CA/RDMD/Watershed and Coastal Resources Division

**Document ID:** 193

**Comment ID:** 180

**Comment:**

Determinations of beach use intensity should be done on an intrastate basis, where each State would categorize its most frequently used coastal recreation waters as designated bathing beach waters and all others in comparison to those beaches.

**Organization Name:** King County Department of Natural Resources and Parks

**Document ID:** 204

**Comment ID:** 338

**Comment:**

Also we do not feel that an interstate approach of weighting of recreational areas is appropriate, again because the types of recreation in the different parts of the country are so different. They are not just different in intensity or numbers of population undertaking them; they are very different in their very nature (e.g. kayaking verse swimming). Therefore determining the confidence level a SSM by comparing the various interstate differences is not appropriate.

**Organization Name:** Massachusetts Department of Environmental Protection

**Document ID:** 208

**Comment ID:** 62

**Comment:**

Categories based on use should be determined from intra-state rather than national figures.

**Organization Name:** Mississippi Department of Environmental Quality

**Document ID:** 207

**Comment ID:** 101

**Comment:**

We believe Mississippi's Beach Monitoring Task Force should have maximum flexibility in determining acceptable risk levels and SSMs appropriate to our beaches. Related to this, we believe that use intensity definitions should be applied using an interstate (national) comparison of frequency of use or the states should have the option of either interstate or intrastate comparisons. Our initial use surveys of Mississippi's beaches confirm that use intensity is not high compared to beaches in other states. For example, on our beaches bathers are not found "shoulder-to-shoulder" on the beach nor in the water as in pictures we have seen of beaches in other states. This is for a number of reasons, but principally because our beaches are man-made and separated by a series of barrier islands from the beautiful waters of the Gulf of Mexico. We

believe it would be unfair to require us and other states to have beaches that range from high to low use. Since beach use intensity is relative, only comparing beach usage within a state does not truly reflect health risks (e.g., within a state a high use beach may only be 100 bathers and a low use beach 10 bathers). Consequently, the states should make use intensity determinations based on local knowledge and experience with their beaches and how those beaches are used and the known health risks.

**Organization Name:** South Carolina Department of Health and Environmental Control Bureau of Water

**Document ID:** 161

**Comment ID:** 221

**Comment:**

**Intrastate vs. Interstate Determinations of Use Frequency.**

We believe that each state should determine the appropriate SSM, based on intensity of use, with interstate comparisons. We know South Carolina's Grand Strand has extremely high use and the SSM should reflect that. However, Gulf Coast beaches in Mississippi and Alabama, perhaps the most heavily used in their states, do not receive nearly the use as the Grand Strand. Accordingly they should have an SSM to reflect that in comparison to the most heavily used beaches in the region or nation.

**Organization Name:** State of Alaska Department of Environmental Conservation/Division of Water

**Document ID:** 175

**Comment ID:** 156

**Comment:**

**Intrastate v. Interstate Determinations of Use Intensity.**

Contrary to the EPA proposal, Alaska supports interpretation of use intensity on a national basis - termed the "interstate" option. Actual risk is a function of absolute - not relative - use intensity (i.e., risk increases directly with the number of users). We suggest that interpretation of use intensity on a national basis will yield lower use intensity designations for cooler states, appropriately reflecting the lower risk in those states. While we support a national basis for interpreting use intensity, we suggest that actual determinations be made by the states in association with CWA actions. Given the cold temperatures, limited access, and vast expanse of Alaska's coastal waters we expect that the overwhelming majority of use intensity determinations would fall under the least intensive use designation, appropriately reflecting the very low risk associated with contact recreation in the vast majority of our coastal waters.

In establishing nation-wide categories based on use intensity, EPA should include quantitative terms in the definitions of the use categories. The definition of each category should express use intensity in terms such as "person-days." This will provide the specificity needed for consistent application of the definitions in association with CWA actions.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 379

**Comment:**

None of these alternatives truly makes any sense. Shouldn't EPA be concerned over the total number of illnesses in a state? Why is proportionality more important than overall protection? EPA seems overly occupied with trying to figure out how to use their single sample maximum recommendations in this rule. Given EPA is using policy values that have no direct relationship to public health, and given that none of EPA's alternatives would provide for a consistent interpretation between states, we recommend that none of these alternatives be included in the final federal rule. As we have stated previously, the EPA rule should be focused on achieving compliance with the geometric mean rather than making the single sample maximum the primary focus. We previously suggested the simplified approach that Washington uses to regulate in consideration of the 90<sup>th</sup> percentile when greater than 10 samples exist and using a single sample maximum when less than 10 samples exist. The focus again should be on the geometric mean and the selection of the single sample maximum value should be stringent enough to encourage adequate data collection.

**Response:**

See preamble at IV.B.5., Intrastate vs. Interstate Determinations of Use Intensity.

## Issue: Louisiana

**Organization Name:** Louisiana Department of Environmental Quality

**Document ID:** 169

**Comment ID:** 317

**Comment:**

Using EPA's guidance, LDHH has identified Louisiana's coastal recreation waters, and those areas within coastal waters that can be classified as coastal recreation beaches consistent with the BEACH Act. It would be appropriate for EPA to consider the information contained within LDHH's report entitled, "*Louisiana's BEACH Grant Final Report Grant Year 2001*", which was completed and submitted to EPA during the summer of 2003, in response to the proposed rule of July 9, 2004. Both LDEQ and LDHH believe the report represents the best information based on the current guidance to use toward developing appropriate bacteria criteria for Louisiana's unique coastal recreation waters. Approaches on how DEQ and DHH will use information from the BEACH Grant Report to develop credible water quality standards to protect Louisiana's coastal recreation waters and human health are described in the following Specific Comments section. The entire report can be found on LDHH's Beach Monitoring Program website at [www.ophbeachmonitoring.com](http://www.ophbeachmonitoring.com).

**Organization Name:** Louisiana Department of Environmental Quality

**Document ID:** 169

**Comment ID:** 319

**Comment:**

The LDHH BEACH Monitoring Program results and the LDHH Louisiana's BEACH Grant Report FY 2001 should be used to identify Louisiana's coastal recreation waters and beaches consistent with the BEACH Act.

Louisiana has been developing a monitoring program for coastal recreation beaches since the BEACH Act became effective during 2000. Under the Clean Water Act (CWA) 406, the Louisiana Department of Health and Hospitals (LDHH) was the recipient of a grant from EPA Region 6 to develop and implement Louisiana's Beach Monitoring Program in accordance with EPA's Program Performance Criteria. The LDHH also recognized that the implementation of Louisiana's Beach Monitoring Program would be further enhanced by collaboration with the Louisiana Office of State Parks and Historic Sites (OSP). LDEQ was consulted for water quality data and technical guidance, and the Lake Pontchartrain Basin Foundation (LPBF) is also partner on monitoring efforts in Lake Pontchartrain.

Louisiana's Beach Monitoring Program and methodology is documented in the LDHH report entitled, "*Louisiana's BEACH Grant Final Report Grant Year 2001*", which was completed and submitted to EPA during the summer of 2003. The report was also public noticed in the Potpourri section of the *Louisiana Register*, the state's official medium for making administrative law documents public. In this report, LDEQ's Water Quality Management Basin subsegments (see LAC 33:IX.1123.A) were used as the basis, along with other decision criteria, to identify Louisiana's "coastal recreation waters" which are listed in Appendix 1 ([www.ophbeachmonitoring.com](http://www.ophbeachmonitoring.com)). These subsegments are currently designated in the Water Quality Standards for primary and secondary contact recreation uses. Primary contact criteria apply during the recreational period of May 1 through October 31.<sup>1</sup>



**Footnote**

<sup>1</sup> A map of the coastal recreation waters for BEACH Act purposes is included as Figure 2.1 in the report.

**Organization Name:** Louisiana Department of Environmental Quality

**Document ID:** 169

**Comment ID:** 323

**Comment:**

**Application of EPA's 304(a) Ambient Water Quality Criteria for Bacteria at Louisiana's "Bathing Beaches."**

The water quality criteria used for Louisiana's BEACH program tiered beaches are:

	Fecal coliform	Enterococci
Geometric Mean Maximum	200 cfu/100 mL	35 cfu/100 mL
Single Sample Maximum	400 cfu/100 mL	104 cfu/100 mL

The BEACH program's water quality classification decision rule is described in Chapter 3 of the LDHH report, and LDHH implements appropriate public notification and risk communications provisions as described in Chapter 4.

LDEQ and LDHH are in the process of reviewing the beach monitoring data collected to date. LDEQ and LDHH have not yet reached the point to suggest whether the use of a single sample maximum value and/or a geometric mean as a part of the bacteria criteria would be appropriate for "coastal recreational waters" in Louisiana. LDEQ and LDHH may have further options to suggest or defend in the near future. It is clear that the "coastal recreation waters" as defined in the LDHH report should not have the same criteria and assessment procedures as those applicable to waters adjacent to "bathing beaches." LDEQ and LDHH will be summarizing and analyzing all of the beach monitoring water quality data for this swimming season and LDHH will be providing an annual report to EPA Region 6 in accordance with the grant performance criteria to EPA.

**Organization Name:** Louisiana Department of Environmental Quality

**Document ID:** 169

**Comment ID:** 324

**Comment:**

**III.B.3.** Currently, based on the available EPA guidance and LDHH beach monitoring (and analytical) data collected to date, LDEQ considers enterococci as the best indicator organism for Louisiana's coastal recreation waters and beaches. This effort is complicated by the fact that many of Louisiana's transitional coastal waters fluctuate in levels of salinity. Also, Louisiana has a limited amount of data available describing the suitability of *E. coli* as a pathogen indicator in its fresh waters. Therefore, it would be appropriate in Louisiana's case to allow the state to implement the best indicator for the water body type.

**Organization Name:** Louisiana Department of Environmental Quality

**Document ID:** 169

**Comment ID:** 418

**Comment:**

The enterococci criterion consistent with EPA's 1986 bacteria criteria document is being applied for advisory purposes (i.e., geometric mean maximum of 35 col/100 ml and single sample maximum of 104 col/100 ml) along with fecal coliform. Therefore, it is strongly emphasized that while LA has not yet adopted the EPA recommended bacteria criteria into its water quality standards, the 304(a) criteria for bacteria are being implemented in LDHH's decision rule for Louisiana's BEACH Monitoring Program at three pilot beaches, and by 2005 will be fully implemented at all beaches.

The LDHH will use the CWA at 406 grant funds awarded to them to continue development of Louisiana's Beach Monitoring Program. LDEQ has worked closely with LDHH in the development of its monitoring program and in the process of determining whether the enterococci criterion levels recommended by EPA Region 6 (based on draft guidance dated November, 2003) are appropriately protective of Louisiana coastal recreation waters. It is anticipated that EPA will also continue to support the state's beach program efforts and work closely with Louisiana towards fulfillment of the federal BEACH Act requirements.

**Organization Name:** State of Louisiana Department of Environmental Quality

**Document ID:** 171

**Comment ID:** 170

**Comment:**

Louisiana is striving towards the adoption of appropriate criteria and standards for its unique coastal waters, but has not promulgated the newly mandated criteria for enterococci as an indicator for the following reasons:

- The uniqueness of Louisiana's coastal waters, e.g., natural turbidity, tidal fluctuation, and variability associated with beneficial diversion or restoration projects
- Lack of data specific to Louisiana waters for fecal coliform and enterococci as indicators, including but not limited to impacts on water quality monitoring and assessment methods already in use
- Results of the recently launched EPA-approved and funded Louisiana BEACH monitoring program developed by the Louisiana Department of Health and Hospitals (LDHH) are an important component of Louisiana's bacteria criteria development
- Consensus between LDEQ and LDHH on the appropriate pathogen indicator

These concerns are described in more detail in a letter to Mr. Miguel Flores, EPA Region 6 dated April 10, 2004, and signed by the Secretaries of LDEQ and LDHH. A copy of the letter is included for your convenience.

**Response:**

EPA recognizes that some states regulate public bathing beaches through their Department of Health requirements. However, Section 303(i) of the Clean Water Act is clear that states must adopt water quality criteria and standards for coastal recreational waters that are as protective of human health as the EPA 1986 bacteria criteria. Moreover, States with BEACH Act implementation grants for monitoring and notification programs must use the applicable water

quality standard, i.e., the water quality standard that protects the waterbody for swimming, bathing, surfing, and similar water contact activities.

This final rule applies to coastal recreation waters, as discussed in preamble to the final at section IV.A., Application of the Rule to Coastal Recreation Waters. Fresh waters designated as primary contact recreation (other than the Great Lakes) are not included in this final rule. States and Territories have discretion in designating waters for primary contact recreation; marine and Great Lakes waters designated by a State or Territory for primary recreation are considered coastal recreation waters.

EPA appreciates the activities by the Louisiana Department of Environmental Quality and Department of Health and Hospital to define beaches for monitoring and notification. However, as the commenter points out, it is the subsegments in the Louisiana Water Quality Management Plan with primary contact uses designated in the Louisiana water quality standards that identify coastal recreation waters.

EPA acknowledges the concerns of the commenter in how the State of Louisiana states a guarantee mean and SSM for coastal recreation waters. However, the obligation of Section 303(i) is clear that if a state does not adopt water quality criteria for pathogens or pathogen indicators as protective as EPA's criteria for pathogens or pathogen indicators, EPA must propose criteria for the state. The rule does that. Louisiana has the ability to consider all factors and adopt water quality criteria that are as protective as EPA's criteria. EPA will work with Louisiana in its transition to adoption of the Federal bacteria criteria.

EPA thanks the commenters who provided information on progress toward full compliance with the BEACH Act requirements.

## Issue: Maine

**Organization Name:** State of Maine Department of Environmental Protection

**Document ID:** 240

**Comment ID:** 88

### Comment:

The following comments are provided by the Maine Department of Environmental (MEDEP). Maine generally supports the purpose and design of this proposed rule and offers the following comments in demonstration of the State's intent to fulfill the purposes of this rule and the overall goals of the BEACH Act of 2000. On April 19, 2004, the MEDEP received a letter from Benjamin Grumbles, Acting Assistant Administrator advising that Maine "has adopted criteria for these pathogen indicators as recommended by EPA's 1986 criteria." The proposed rule appears to contradict that finding. It is our opinion that Maine standards, and the means by which they are implemented, provide protection for recreation users well in exceedence of that afforded by the proposed rule.

Maine's recommendation is:

- for Maine to retain its present numerical enterococci standards for SB and SC waters and narrative standard for Class SA
- to allow Maine to proceed with planned pending revisions to Class SB and SC bacteria standards and retain primacy in rulemaking.

### History:

It is believed that Maine was the first state to adopt enterococci standards for its coastal waters. Our adoption occurred prior to the publication of EPA's Water Quality Criteria for Bacteria-1986. From 1984-86, Maine was developing a comprehensive revision of its water quality standards. In consultation with EPA researchers who were working on the EPA's criteria document, Maine elected to adopt new enterococci and *E. coli* standards for all its waters for the beneficial reasons stated in that document and further elaborated in this proposed rule. Since Maine already had fecal coliform standards that exceeded the EPA recommended criteria of the time, the State calculated new enterococci criteria that it deemed to provide a similar expected risk level as the former FC criteria. As a result, Maine's enterococci criteria are more stringent than any of EPA's recommended criteria finally adopted in 1986 and proposed in this rule (Maine's Class SB water establishes a geometric mean of 8 cfu/100ml and single sample maximum of 54 cfu/100ml; Class SC establishes a geometric mean of 14 cfu/100ml and single-sample maximum of 94cfu/100ml.). Maine has assigned primary recreation ("recreation in and on the water") as a designated use for all its surface water classes.

**Organization Name:** State of Maine Department of Environmental Protection

**Document ID:** 240

**Comment ID:** 93

### Comment:

Secondly, Maine's recreational bacteria standards apply only in warm weather. The proposed rule is silent on Maine's use of seasonal limits and, we therefore, presume that it is an allowable practice for a state to determine its recreation season. Maine coastal waters are notoriously cold, during the great majority of days within the current specified season of May 15 to September 30 water temperature does not exceed 60 degrees Fahrenheit. It should also be noted that because of

the cold temperature, individual contact time in the water is far less in Maine than would be anticipated in more southerly states, further contributing to a reduced risk factor.

It should further be noted that Maine has traditionally applied its ambient bacteria Criteria also as effluent criteria. There is no allowance for dilution in establishing effluent limits, thus, any compliant facility attains the ambient criteria immediately at its outfall. Dilution that does occur in the receiving water further reduces risk of exposure.

**Organization Name:** State of Maine Department of Environmental Protection

**Document ID:** 240

**Comment ID:** 482

**Comment:**

The MEDEP agrees with EPA's interpretation of the narrative bacteria standard for Class SA waters, and that these waters do not require inclusion in this rule.

**Response:**

For information on specific States and Territories, see the preamble to the final rule at section V.B., Which States and Territories are Included in Today's Rule?

Federal water quality standards regulations at 40 CFR 131.10(f) allow for seasonal uses, provided the criteria adopted to protect such uses do not preclude the attainment and maintenance of a more protective use during the recreational season. Several States and Territories, such as Maine, have adopted, and EPA has approved, primary contact recreation and associated water quality criteria only for those months when primary contact recreation occurs and have relied on less stringent secondary contact recreation water quality criteria to protect for incidental exposure in the "non-swimming" season. Furthermore, today's rule at 40 CFR 131.41(d)(2) allows states to apply their general rules of applicability to the promulgated criteria, including the decision by a state to apply the criteria as effluent limits.

In assessing the protectiveness of State and Territorial water quality standards prior to April 10, 2004, EPA sent letters to all 35 coastal and Great Lakes States and Territories informing them of EPA's initial review. Several States and Territories, including Maine, received letters commending their efforts and informing them that EPA's initial review of their standards was favorable. EPA also stated in the letter that the Agency was continuing its review of all State and Territorial water quality standards "to determine full compliance with the BEACH Act." Upon further review of Maine's bacteria criteria, EPA determined that the criteria did not apply to coastal recreation waters with non-human sources of enterococci.

EPA recognizes that some States and Territories are in the process of adopting water quality standards to be as protective of human health as EPA's 1986 bacteria criteria. Once a State or Territory submits the adopted Standards to EPA, The Agency will use CWA sections 303(c) and 303(i) to guide its review of the standards. Water quality standards do not become effective for Clean Water Act purposes until EPA approves them (40 CFR 131.21). Once EPA approves a State's or Territory's standards as being as protective of human health as EPA's 1986 bacteria criteria, those will become the applicable water quality standards even before EPA undergoes rulemaking to remove that State or Territory from 40 CFR 131.41. Today's rule does not impede the planned actions by the State of Maine to revise its criteria for Class SB and SC waters.

EPA thanks the commenters who provided information on progress toward full compliance with the BEACH Act requirements.

## **Issue: Mississippi**

**Organization Name:** Mississippi Department of Environmental Quality

**Document ID:** 207

**Comment ID:** 100

### **Comment:**

As noted in the proposed rule, Mississippi has yet to adopt criteria consistent with EPA's 1986 bacteria criteria. We currently use fecal coliform criteria and have found them protective of our coastal beaches. However, we do plan on adopting enterococci criteria as recommended in EPA's 1986 guidance. In all other ways, we are in compliance with the Beach Act. Since 1998, we have conducted extensive monitoring of our coastal beaches testing our waters for enterococci, fecal coliform, and various chemical parameters. At the same time we began testing our beach waters, we formed a Beach Monitoring Task Force. The task force members include the Mississippi State Department of Health, the Department of Marine Resources, the Gulf Coast Research Laboratory, and the EPA Gulf of Mexico Program. We also started a public notification program where we advise the public when coastal waters have unacceptable levels of bacteria. To date, there have been no known disease outbreaks as a result of bathers using our coastal waters. Please visit our Beach Monitoring Webpage at <http://www.usm.edu/gcrl/msbeach/> for more information on our beach monitoring program. This summer we are conducting beach use surveys to determine beach use intensity and hence, the appropriate single sample maximum (SSM) for our coastal beaches.

### **Response:**

EPA recognizes that some states regulate public bathing beaches through their Department of Health requirements. However, the BEACH Act is clear that states must adopt water quality criteria and standards for coastal recreational waters. Moreover, States with BEACH Act implementation grants for monitoring and notification programs must use the applicable water quality standard, i.e., the water quality standard that protects the waterbody for swimming, bathing, surfing, and similar water contact activities.

EPA thanks the commenters who provided information on progress toward full compliance with the BEACH Act requirements.

## **Issue: New Indicators, Methods, and Science**

**Organization Name:** American Forest and Paper Association

**Document ID:** 191

**Comment ID:** 191

**Comment:**

As a general matter, EPA should structure the standards to promote the use of sound science.

**Organization Name:** American Society for Microbiology

**Document ID:** 162

**Comment ID:** 38

**Comment:**

The ASM appreciates the importance of EPA's use of indicator species and the need to relate numbers of indicator species to risk of illness. The EPA has proposed fecal coliforms, enterococci and *E. coli* as suitable indicators, and established geometric mean and "single sample maximum" concentrations of each that are associated with acceptable risks of gastrointestinal illness in recreational waters used with different frequencies. In addition, the EPA has devoted considerable effort to developing suitable sampling and analytical protocols for indicator organisms in recreational waters.

Unfortunately, the ASM is concerned that the proposed rule may provide inadequate control of microorganisms that pose significant threats to human health through contamination of recreational waters.

**Organization Name:** City of New York Department of Environmental Protection

**Document ID:** 241

**Comment ID:** 57

**Comment:**

The Beaches Environmental Assessment and Coastal Health Act of 2000 requires EPA to conduct studies which may result in revised criteria for coastal recreation waters. It is understood that EPA has begun this effort. When these investigations are completed, it is possible, if not likely, that a new pathogenic indicator may be recommended for use resulting in revised criteria. Consequently, the final rule may promulgate requirements which are, therefore, interim in nature. More simply put, the target may move.

It is extremely difficult for large utilities such as NYCDEP to effectively plan for changing criteria given the complexities of the compliance process cited above. It is much more effective from an engineering and cost standpoint for the City of New York to understand fully what is required to attain water quality uses and criteria. The City of New York and other large discharges may have a number of technical options which can be considered for compliance with water quality-based requirements. Unless the ultimate water use/water quality impact reduction goal is clearly identified in quantitative terms, piecemeal efforts to attain interim targets may severely hamper, if not prevent, a fully cost effective solution on the part of the discharger.

We therefore recommend that the final rule establish recommended criteria for the management and regulation of bathing beaches, on an interim basis, but that TMDLs, NPDES requirements and waterbody compliance assessments be deferred until EPA completes its studies and either confirms or revises criteria for coastal recreation waters.

We appreciate the effort that the Agency is making to protect the public health and to apply uniform criteria nationally. We sincerely appreciate the opportunity to comment on the proposed rule making. We would be pleased to provide any additional information which you may require.

**Organization Name:** Fraser Papers

**Document ID:** 165

**Comment ID:** 105

**Comment:**

Fraser Papers Supports the Concept of Revising Bacterial Water Quality Criteria

Fraser Papers supports the concept of revising bacterial water quality criteria for contact recreation waters for beaches and coastal areas, to make these criteria more directly associated with bacterial species associated with waterborne illness. Fraser Papers also supports EPA's description of the new criteria as "based on indicator [emphasis added] bacteria, namely, *Escherichia coli* (*E. coli*) and enterococci..."(69 FR 41722).

**Organization Name:** Massachusetts Department of Environmental Protection

**Document ID:** 208

**Comment ID:** 67

**Comment:**

While the protective public health position is to consider indicators from all sources as measures of risk, given the current state of the science, EPA should be leading the effort to quantify the risk of disease based on indicators from non-human sources through more rigorous and extensive studies. This is a national issue and not state specific for the most part.

**Organization Name:** New York State Department of Environmental Conservation

**Document ID:** 218

**Comment ID:** 89

**Comment:**

Need for Revised Criteria by October 2005 Deadline.

New York recognizes the 1986 criteria as interim values, that do not replace our need to retain and implement coliform standards to protect for shellfish harvesting and other designated uses. We look forward to the publication of revised national bacteria criteria in October 2005, as required of the USEPA under the BEACH Act.

**Organization Name:** North Carolina Dept. of Environment and Natural Resources

**Document ID:** 190

**Comment ID:** 464

**Comment:**

*Scientific Validity*

Since the release of the 1986 criteria, we have commented frequently on the inadequacy of the epidemiological and environmental assessments used to support the criteria. Even the recent peer review conducted by EPA (Versar, 2004) continues to challenge the scientific validity of the proposed promulgation. Clearly, new science is needed. We remain concerned, given our



relatively unpolluted beaches in North Carolina, that EPA 's coastal promulgation efforts are based on studies that did not find ANY statistically significant swimming-associated gastroenteritis at any of the relatively unpolluted beaches (1986 Ambient Water Quality Criteria for Bacteria, page 4).

**Organization Name:** North Carolina Dept. of Environment and Natural Resources

**Document ID:** 190

**Comment ID:** 467

**Comment:**

In conclusion, North Carolina strongly believes that federal promulgation of "Water Quality Standards For Coastal and Great Lakes Recreation Waters" is *premature*. The US EPA has failed to answer questions regarding the validity of the science and has failed to adequately address interpretations of terminology within the proposed rule. We request that further promulgation action be delayed until such time as the science can support the standard development.

**Organization Name:** Oregon Department of Environmental Quality

**Document ID:** 174

**Comment ID:** 69

**Comment:**

DEQ believes that EPA should provide further explanation for the need to promulgate bacteria at this time. Several EPA guidance documents indicate that EPA will propose new bacteria criteria in October 2005.

**Organization Name:** Pennsylvania Department of Environmental Protection

**Document ID:** 233

**Comment ID:** 247

**Comment:**

First, we echo a comment made on several occasions by ASIWPCA on behalf of the states. By EPA's own admission in several conference call meetings, the 1986 criteria are limited and dated in the science used to derive them. Section 3 of the BEACH Act of 2000 requires development of a superior bacterial indicator by October 10, 2005 according to revised sections 104(v) and 304(a)(9) of the Federal Water Pollution Control Act (33 U.S.C. 1254, and 33 U.S.C. 1314(a)(9), respectively). It appears illtimed, at best, to so heavily focus on promulgating twenty-year-old criteria when more current science is available and under consideration in the criteria that should be under development at this same time.

**Organization Name:** State of Louisiana Department of Environmental Quality

**Document ID:** 171

**Comment ID:** 171

**Comment:**

As you know, EPA is in the process of evaluating exposure to and effects of microbial pathogens in marine and fresh recreational waters as required by Section 3(a)(v)(1) of the BEACH Act. The information collected by EPA will be used to estimate the relationship between water quality indicators, water quality parameters, and health effects. However, according to your Clean Beaches Plan, recommendations for new water quality criteria based on these epidemiological studies will not be available until the statutory deadline in October 2005. It is feasible that new recommendations will require states to again change their water quality standards. Since this

department has not had sufficient time or resources to determine if the enterococci criterion recommended by EPA Region 6 (based on draft guidance dated November, 2003) is actually appropriate for Louisiana coastal recreation waters, LDEQ will not adopt a criterion that may not be representative or protective of Louisiana's unique coastal waters. The new EPA guidance has not been finalized, and at this point it is not clear how much flexibility coastal states will have in developing and implementing appropriate bacteria criteria into their water quality standards. In spite of these obstacles, be assured that LDEQ's goal is to adopt the best criteria to assure that Louisiana's coastal water quality is safe and protective of designated uses.

**Organization Name:** William Hastback

**Document ID:** 157

**Comment ID:** 276

**Comment:**

Isn't this putting the cart before the horse? Why are they proposing to adopt specific enterococcus standards (page 24 or the review draft) if they haven't yet started their studies?

Again, this seems absurd, yet they expect to have this mess adopted and the new standards in effect within three years, requiring new unspecified enterococcus standards for discharges permitted under SPDES. All of which could change if the studies that they are either doing now or plan on doing in the future determine that different indicators or different enterococcus standards are more appropriate.

**Response:**

See the preamble to the final rule at section VI.A., 1986 Bacteria Criteria.

EPA notes that all CWA 304(a) recommended criteria are subject to revision as new information becomes available that indicates revisions are necessary. The BEACH Act allows states and territories three years to adopt any new or revised criteria.

In addition, as part of its requirements under CWA section 304(a)(9), EPA is working on developing new criteria, and expects to publish those criteria by October 2005. Epidemiological studies currently underway to determine these criteria will capture many types of endpoints, including gastrointestinal disease. These studies will also statistically evaluate sampling strategies, data analysis, and management techniques to determine acceptable levels of fecal contamination. These studies will also examine representativeness and applicability of the bacteria criteria on a national level. Once the new criteria have been developed, EPA will collect input from a wide range of stakeholders, in the same way that comment has been solicited and incorporated into criteria historically. TMDLs, National Pollutant Discharge Elimination System water quality-based effluent limitation permit requirements, and water quality assessments under the Clean Water Act must be based on currently effective water quality standards, as provided in the Clean Water Act. EPA does not have the authority to defer these actions in this rulemaking.

**Issue: New York****Organization Name:** City of New York Department of Environmental Protection**Document ID:** 241**Comment ID:** 52**Comment:**

Reference is made to the proposed rule to establish water quality criteria for bacteria for coastal recreation waters in specific States and Territories published in the Federal Register on July 9, 2004. The proposed amendments of 40 CFR Part 131 are being undertaken in order to comply with the requirements of Section 303(i) of the Clean Water Act which requires, by April 10, 2004, that States and Territories with coastal recreation waters adopt water quality standards for bacteria that are as protective of human health as the Environmental Protection Agency's (EPA) 1986 recommended bacteria criteria<sup>1</sup>. The State of New York has not yet adopted criteria consistent with EPA's 1986 bacteria criteria, and is therefore included in the proposed rule making. As New York City's bathing beaches and some of the City's waters would be subjected to the bacteria rule, the New York City Department of Environmental Protection (NYCDEP) is very interested in the details of the rule making surrounding the adoption of the new bacteriological indicator.

NYCDEP and the New York City Department of Health and Mental Hygiene have jointly submitted comments by separate letter on the technical and application aspects of the proposed rule that impact both Departments. The purpose of this letter is to submit comments on aspects of the proposed rule that are of particular interest to this Department.

**Footnote:**

<sup>1</sup>USEPA. 1986. Ambient Water Quality Criteria for Bacteria -1986. EPA-440/5-84/002.

**Organization Name:** The City of New York Department of Health and Mental Hygiene**Document ID:** 239**Comment ID:** 137**Comment:**

On July 9, 2004, the Environmental Protection Agency, in the Federal Register (Vol 69, No. 131), proposed to establish water quality criteria for bacteria for coastal recreation waters in specific States and Territories. The States and Territories covered by this proposed rule do not have water quality standards for bacteria that comply with the requirements of Section 303(i) of the Clean Water Act (CWA). The New York State Department of Environmental Conservation (NYSDEC) has not yet adopted beach and recreational (primary contact) water quality criteria consistent with the CWA. NYSDEC anticipates state adoption of the proposed rule in 2005. Consequently, this proposed rule would impact New York City's beach and recreational water quality criteria. Therefore, the proposed rule carries great importance and is of major concern to the New York City Departments of Health and Mental Hygiene (DOHMH) and Environmental Protection (DEP).

Water quality criteria are used by DOHMH to assess the water quality conditions and to make determinations of beach classifications ("Advisories", "Open" or "Closed"), and are used by DEP to assess the adequacy of current water quality conditions and to guide the planning and construction of needed water pollution control facilities. Hence, both Departments are very interested in the details of the rule making surrounding the adoption of the new bacteriological indicator. It is possible that adoption of the new bacteriological indicator as a water quality

criterion of the state could result in future unnecessary regulatory action with costly expenditures. Our interest, therefore, is to review proposed water quality criteria and standards changes to ascertain that they are properly based from a technical and regulatory standpoint and necessary for protection of the public health, safety and the environment.

**Response:**

EPA recognizes that some states regulate public bathing beaches through their Department of Health requirements. However, Section 303(i) of the Clean Water Act is clear that states must adopt recommended criteria into their water quality criteria and standards for coastal recreational waters that are as protective of human health as the EPA 1986 bacteria criteria. Moreover, States with BEACH Act implementation grants for monitoring and notification programs must use the applicable water quality standards, i.e., the water quality standards that protect the waterbody for swimming, bathing, surfing, or similar water contact activities.

EPA thanks the commenters who provided information on progress toward full compliance with the BEACH Act requirements.

**Issue: Non-Human Sources****Organization Name:** Buckeye Florida**Document ID:** 172**Comment ID:** 244**Comment:**

*Do the Standards Exempt Fecal Contamination From Non-Human Sources* - The proposed rule is for fecal contamination indicators and not for the actual associated pathogens. Even though this proposed standard is much better than historical total or fecal coliform based standards implemented in many States, there are still cases where *E. coli* and enterococci tests can show elevated results without any fecal contamination present. Buckeye supports EPA's intent to make provisions in the rule to allow for an expert bacteriological water quality assessment if limits are exceeded to determine if the source of the bacteria is non-human and not a health risk. EPA further presented recent studies that "suggest" there might be a risk posed to humans as a result of exposure to non-human fecal contamination. Buckeye believes these results are definitive at this time and supports an approach that requires only sanitary surveys before excluding non-human sources.

**Organization Name:** Florida Department of Environmental Protection**Document ID:** 229**Comment ID:** 78**Comment:**

In Florida we have observed high bacteria levels in waters with no known anthropogenic inputs. We support a provision to allow States to disregard bacteria from wildlife and environmental sources (plants, sediments) when a sanitary survey determines that there are no anthropogenic sources of bacteria present. We believe requiring epidemiological studies at these sites will be economically prohibitive, unreasonable, and unnecessary.

**Organization Name:** Florida Department of Health**Document ID:** 230**Comment ID:** 13**Comment:**

We are concerned that allowance of exclusion of non-human indicators in lab work and criteria establishment may be the wrong direction for EPA and states. We would support your contention in this federal register that many waterborne disease outbreaks have been caused by pathogens excreted by animals. Numerous animal source emerging pathogens have been newly detected and many older ones have appeared to increased in pathogenicity and have been more readily identified in water. As improving lab methods, epidemiology, etiology identification, and diagnosis of these infectious diseases affect recognition of those that cause waterborne illnesses, we must remain diligent and conservative in our approaches to protecting public health. Relatively new phenotypic and genotypic methods for defining sources of human versus non-human pathogens in surface water have been shown to have significant error possibilities (Journal: Drinking Water and Health, December, 2003) that hamper a water manager's ability to discern public health risk. We agree that the MMWR reports and others you have listed are appropriate evidence that animal sources of fecal pollution are just as important (if not more so) than human fecal pollution. Until the EPA's or other's field work and analysis provides a scientific preponderance of evidence that animal sources are of negligible concern, we will continue to count all indicator colonies toward the geomean and the SSM.

**Organization Name:** Hampton Roads Sanitation District

**Document ID:** 220

**Comment ID:** 461

**Comment:**

The state of the art of bacterial knowledge has advanced significantly since the data generation in the 1970's and since criteria publication in 1986. The methods of enumeration have been improved to eliminate the old problems which had unknown affect on the generated conclusions. Further it is now possible to routinely and economically determine the source of fecal indicator organisms. Fecal organisms are typical of fecal contamination from human, avian, pets, livestock and wildlife. Human source is an obvious problem in need of immediate correction. Studies used to generate the criteria were conducted only in areas known to have human pollution problems. Recent studies conducted throughout Virginia in areas of elevated enterococci levels have routinely identified highly significant influences on the perceived bacterial counts from natural sources like geese, sea gulls and wild life. There are no studies cited by the EPA to confirm human health problems conveyed from any of these sources. These obviously and easily determined nonhuman affected numbers must carefully be considered when evaluating relative to control and potential enforcement actions based solely on enumeration of total enterococci concentrations.

**Organization Name:** King County Department of Natural Resources and Parks

**Document ID:** 204

**Comment ID:** 334

**Comment:**

It is possible that avian sources are significant sources of enterococci and yet have little consequence for human health risk, particularly for the human viruses, the organism EPA concluded enterococci represents well. In urban areas with large resident populations of waterfowl and seagulls, it is likely that their influence on waterbodies bacteria counts could be large but unrelated to the epidemiological study results focused on human health risks.

**Organization Name:** New Jersey Department of Environmental Protection

**Document ID:** 178

**Comment ID:** 26

**Comment:**

**Human vs. non-human fecal pollution sources**

Because human fecal waste may contain, in addition to cross-species pathogens, pathogens that are human-specific and human-adapted (*e.g.*, *Vibrio cholera*, *Shigella* spp., *Entamoeba histolytica*, and many viral pathogens), human fecal pollution in recreational waters is believed to be more hazardous to humans than is fecal pollution from animals. Also, as summarized in the Proposed Rule, there have been a number of documented human disease outbreaks in recent years due to pathogens from domestic animals and far fewer recorded outbreaks due to pathogens from indigenous or wild animals. Hence, it is generally accepted that the comparative human health risk of these fecal sources is (high to low): human > domestic animal > indigenous (wild) animal. However, the amount or degree of difference in health risk is unknown and not likely ever to be known with any certainty.

When the bathing beach epidemiological studies were conducted between 1972 and 1982 that resulted in the 1986 water quality criteria, demonstrable adverse health risks were established. It was presumed that human waste was a component of the fecal pollution to which the bathers were exposed (and this was undoubtedly true at some or most of the locations studied) but the composition of the pollution present during these studies (% human, % domestic animal, and % wildlife) was not known. Thus, it seems somewhat questionable to say, through this Proposed Rule, that because a particular site today lacks one or another component of pollution (*e.g.*, human?), the health risk must be different (*e.g.*, lower?). Therefore, it is not prudent at this time to make any quantitative distinction as to the degree of health risk from different pollution sources (human, domestic, or indigenous animal) in lieu of additional scientific support. While new methodologies (*e.g.*, coliphage, MAR) are useful to prioritize fecal pollution sources for corrective actions, there are a number of limitations with these techniques for water quality standards application. Thus, the 1986 Gm criteria should apply at this time to waters regardless of the presumed presence or absence of human and/or domestic animal pollution sources.

**Organization Name:** Pennsylvania Department of Environmental Protection

**Document ID:** 233

**Comment ID:** 260

**Comment:**

The final promulgation should allow states to exclude non-human sources of fecal contamination by requiring sanitary surveys which shows the source(s) to be wildlife or that the indicator densities for the non-human source(s) are not indicative of a health risk to those swimming in such waters.

**Organization Name:** South Carolina Department of Health and Environmental Control Bureau of Water

**Document ID:** 161

**Comment ID:** 223

**Comment:**

**Issue:** Exemption from standard due to non-human sources.

As EPA, we believe that some non-human sources may pose human health risks and should not be exempted. However, in areas where wildlife are the only sources, there must be an exception to the standard. This can be accomplished by using higher value for the standard or developing a subcategory of recreational waters with an appropriate standard. Many states already have numerous waters on 303(d) lists where wildlife may be the only contributor. This will ultimately result in development of TMDLs which can not be implemented.

**Organization Name:** State of Alaska Department of Environmental Conservation/Division of Water

**Document ID:** 175

**Comment ID:** 158

**Comment:**

**EPA Review of State and Territorial Standards: Do the Standards Exempt Fecal Contamination From Non-Human Sources?**

The State of Alaska supports exempting wildlife sources of bacteria from the criteria while including domestic animal sources. We agree with EPA that mounting evidence suggests that

fecal contamination of waters by livestock and other domestic animal sources pose health risks, while the risk posed by wildlife is likely substantially less. In effect, the State of Alaska supports option number (3) in the summary of this Part.

**Organization Name:** State of Connecticut Department of Environmental Protection

**Document ID:** 244

**Comment ID:** 163

**Comment:**

One significant issue that was not addressed in the proposed rule is the relationship between the source of indicator bacteria and the health risk to recreational users. Connecticut endorses strict application of the 1986 criteria to waters that are known or potentially could carry human sewage. However, it should be clearly stated that there has been no relationship established between indicator bacteria originating from non-human sources and illness rates. Clearly there is a role for sanitary surveys and other forms of source assessment in the process of making use attainment decisions. EPA should clarify this role and allow for states judicious use of professional judgment and consideration of advanced monitoring techniques such as bacteria source typing when making use attainment decisions.

**Organization Name:** State of Hawaii Department of Health/Environmental Health Administration

**Document ID:** 195

**Comment ID:** 399

**Comment:**

**The State's Preferred Options**

*Wildlife and Non-human Sources:*

Hawaii does have feral animal populations such as rodents, deer, goats, and sheep, and birds, in addition to farm livestock and pets. None of these animals would be considered wildlife for the purposes of this rule; but local marine mammals such as monk seals, dolphins, etc. do qualify as "wildlife". Given that the State does not have significant "wildlife" populations that could potentially contribute to consistently high enterococci contamination in nearshore waters, it stands to reason to exclude them.

**Organization Name:** State of Hawaii Department of Health/Environmental Health Administration

**Document ID:** 195

**Comment ID:** 400

**Comment:**

**The State's Preferred Options**

Hawaii also favors an option of excluding other non-human sources of enterococci contamination based upon appropriate study, which may include a sanitary survey.

**Organization Name:** State of Maine Department of Environmental Protection

**Document ID:** 240

**Comment ID:** 90



**Comment:**

Maine's recommendation is:

- for EPA to adopt proposed option 3 (excluding wildlife sources) for exemption of non-human sources.

**Organization Name:** State of Maine Department of Environmental Protection

**Document ID:** 240

**Comment ID:** 91

**Comment:**

**Application of Maine's criteria**

Aside from the numerical values that Maine has adopted, it is important to further understand the context within which these criteria are applied. Two parts of Maine's standards set them apart from some other states. First, Maine standards apply to enterococci "of human origin." Many sources, most of which are not known to carry human pathogens, will produce organisms that test positive to the enterococci test. In adopting its standards in 1986, Maine intended to disregard exceedences where there were no plausible sources of human pathogens. The proposed rule offers three possible approaches to exempting non-human sources (Section W.A.4). Maine recommends adoption of the third approach ("exclude only wildlife sources"). Maine has routinely interpreted its criteria by assuming that bacteria of human origin unless there are no plausible human sources that could contribute to the test. Many Maine waters are remote, however, even these reference quality waters may occasionally test high for bacteria (as expected of any statistically derived criteria) because of the presence of concentrations of wildlife. We believe that by including source-based information along with test results provides a very protective decision tool without inclusion of all high test results. It is also unclear from management perspective, what actions this agency should take to when the indicator bacteria source is not human or human-caused.

**Organization Name:** State of Maine Department of Environmental Protection

**Document ID:** 240

**Comment ID:** 95

**Comment:**

**Rule Promulgation**

This rule proposes that Maine apply the criteria to all sources, human and non-human for Class SB and SC waters. Maine agrees that the inclusion of domestic animal sources may be warranted as cited in Section IV.4.A. The MEDEP had already proposed to the Maine Legislature in 2003 (LD 1846) to amend its water classification statute to include domestic animal sources of pathogen-indicating bacteria. That bill was not passed, but for reasons unrelated to the amendment regarding bacteria from domestic animal sources. Legislation is already proposed for the next regular session of the legislature that will contain that amendment. This amendment will bring Maine into full compliance with this rule assuming the proposed option 3 in this rule to "exclude wildlife sources" is adopted. Maine disagrees that pathogen-indicating bacteria standards should be applied without reference to source. That would inflate the number of "impaired" waters for Maine and other states, with no documented benefit of reduced risk and with a substantial and impractical burden of controlling all potential sources of enterococci.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 353

**Comment:**

Livestock and pets should be included in any comparison with the criteria.

**Organization Name:** Surfrider Foundation

**Document ID:** 194

**Comment ID:** 123

**Comment:**

**Fecal Contamination from Non-Human Sources**

Surfrider Foundation is concerned about exempting (not applying) the water quality criteria if the sources of bacterial contamination are found to be (or believed to be) nonhuman. Common sense says that swimming, surfing, etc. in fecal contamination of any kind is not a wise thing to do. The proposed rule references studies by the Centers for Disease Control and Prevention and USDA that indicate livestock and domestic animals can transmit human pathogens to surface waters. Furthermore, outbreaks of *E. coli*, *Salmonella*, *Giardia* and *Cryptosporidium* are frequently of animal origin, and there is some evidence that wildlife has been the source of some outbreaks. We agree with the statement in the proposed rule:

"...the increasing number of cases such as those described above, in which animals are suspected of being the likely cause of the contamination and resulting illness present a case for not exempting these sources where human contact or consumption are likely to occur."

We do not believe that bacterial contamination from any animal source should be excluded unless epidemiological studies clearly show that bacteria from that source has no association with the transmission of pathogens to humans.

**Response:**

See the preamble to today's rule, in particular IV.B.7., Addressing Non-Human Sources of Bacteria.

## **Issue: Non-Human Sources 1**

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 352

**Comment:**

An allowance for human bacterial pollution above high natural levels is needed.

**Response:**

EPA recognizes that for other pollutants, especially those with criteria intended to protect aquatic life, States and Territories may consider organisms' ability to adapt to natural conditions that are less stringent than EPA's recommended 304(a) criteria. However, in the case of bacteria criteria to protect human health, certain levels of bacteria, natural or anthropogenic, may cause human illness. EPA has addressed this issue in the preamble to today's rule, in particular section IV.B.7., Addressing Non-Human Sources of Bacteria.

## **Issue: Non-Human Sources 2**

Comments originally listed under this issue have been reassigned to another issue.

## Issue: Non-Human Sources 3

**Organization Name:** American Forest and Paper Association

**Document ID:** 191

**Comment ID:** 455

**Comment:**

AF&PA concurs with NCASI's observation that the implementation of the new water quality standards for coastal and great lakes recreation waters may lead to arduous restrictions on point and non-point sources without benefiting human health. This would occur if the standards do not recognize that positive indicator responses, whether from traditional fecal coliform measures or from the proposed standards based on *E. coli* and enterococci assays, can occur absent the presence of human fecal matter. Under these circumstances, indicator results may be invalid.

**Organization Name:** Fraser Papers

**Document ID:** 165

**Comment ID:** 106

**Comment:**

Fraser Papers Supports the Approach of Providing Exemptions for Excluding from Regulation, Non-Human Sources of Fecal Contamination, Based on Sanitary Surveys

In providing justification for the new criteria, EPA cites an article in the peer-reviewed scientific literature: "In addition, fecal coliforms are sometimes detected where fecal contamination is absent, possibly resulting in inaccurate assessments of recreation safety. For example, *Klebsiella* spp., a bacterial organism that is part of the fecal coliform group but which is generally not harmful to humans, is often present in pulp and paper and textile mill effluents" [Archibald, F. Water Qual. Res. J. Canada 35 (1) 1-22, 2000...] (69 FR 41722).

In this article cited by EPA, the author points out that both *E. coli* and enterococci also have been found in biologically treated pulp and paper mill effluents, in cases with no sanitary sewer connection to the effluent treatment systems. Whether those bacteria are of recent wildlife origin or in fact are associated with the wood furnish is not understood. Because the *E. coli* and enterococci associated with pulp and paper mill effluents have not been shown to be associated with human fecal contamination nor with pathogenic activity, a regulation on their presence in receiving waters with concomitant regulation in pulp and paper mill effluents via NPDES permit conditions is problematic.

EPA addresses a question related to this situation in material contained in the proposal, 67 FR 41729-41731, "Do the Standards Exempt Fecal Contamination from Non-Human Sources?" EPA solicits comment on which of the following possible approaches to reviewing exemptions for non-human sources of fecal contamination should be followed:

- (1) Require sanitary and epidemiological studies before excluding non-human sources;
- (2) Require only sanitary sewer surveys before excluding non-human sources;
- (3) Exclude wildlife sources.

Fraser Papers requests that EPA support approach (2). It is our understanding that in the case of a pulp and paper mill discharging effluent shown to contain *E. coli* and/or enterococci, this might require (a) an examination of the sanitary system within the mill to demonstrate that it does not connect to the process effluent system (or, if it does, that the sanitary effluent is treated so as to

remove bacterial contamination); and (b) a bacteriological examination of samples of the biologically treated total mill effluent to ascertain that it does not contain organisms indicative of human fecal contamination, and that it likely does not contain pathogenic organisms, e.g., performance of tests for *Salmonella* and *Shigella*, examination of isolated strains of *E. coli* using serogrouping and toxin typing, and detection for ST, LT, and VT toxins.<sup>1</sup>

**Footnote:**

<sup>1</sup> This strategy for conducting tests of pulp mill effluents testing positive for *E. coli* or enterococci to demonstrate absence of human fecal contamination and to rule out likely pathogenic contamination is based upon unpublished material prepared by Frederick Archibald, Microbiologist, Pulp and Paper Research Institute of Canada, December, 2001.

**Organization Name:** National Council for Air and Stream Improvement, Inc.

**Document ID:** 189

**Comment ID:** 213

**Comment:**

In providing justification for the new criteria, EPA cites an article in the peer-reviewed scientific literature: "In addition, fecal coliforms are sometimes detected where fecal contamination is absent, possibly resulting in inaccurate assessments of recreation safety. For example, *Klebsiella* spp., a bacterial organism that is part of the fecal coliform group but which is generally not harmful to humans, is often present in pulp and paper and textile mill effluents [Archibald, F., Water Qual. Res. J. Canada 35 (1) 1-22, 2000...] (69 FR 41722). Not mentioned by EPA, but noted by Archibald (and others<sup>2</sup>) is that both *E. coli* and enterococci also have been found in biologically treated pulp and paper mill effluents in cases with no sanitary sewer connection to the effluent treatment systems. Whether those bacteria are of recent wildlife origin or, in fact, are associated with the wood furnish is not understood. Nonetheless, because the *E. coli* and enterococci associated with pulp and paper mill effluents have not been shown to be associated with human fecal contamination or with pathogenic activity, a regulation on their presence in receiving waters with concomitant regulation in pulp and paper mill effluents via NPDES permit conditions is of serious concern.

NCASI is concerned about the lack of validation of these indicator methods on pulp and paper effluent matrices. Although the agency is proposing these bacteriological criteria for ambient waters, indicator assays will be implemented in the context of effluent limitations in NPDES permits. The fact that methods for analyzing effluents have not been validated for wastewater matrices should be made known to the States, so that the criteria will not be implemented until this has taken place. Also, since pulp and paper mill effluents may be analyzed for the fecal indicators, they should be included in the method validation work. It is our understanding that EPA has not completed validation of the new membrane filter methods for the enumeration of *E. coli* 1103, 1603, 1604, and enterococci 1106, 1600 in wastewater matrices, although these methods were proposed in an April 6, 2004 Federal Register notice. EPA's ongoing validation does not include pulp and paper effluent matrices. EPA has indicated that these methods are currently only promulgated for use in ambient waters, and these methods were used to establish the proposed ambient water quality criteria cited in the proposal. Standard Method 9221F, a multi-tube test also proposed in this same Federal Register notice, discusses the interpretation of *E. coli* results and indicates that "a positive control (MUG positive) culture, a negative control consisting of thermotolerant *Klebsiella pneumoniae* (MUG negative) culture and an uninoculated medium control may be necessary to interpret the results ..." Standard Methods also indicates that there are limitations to using membrane filter techniques on complex matrices. These

recommendations should be addressed, and the validation studies should be completed, before the States are charged with implementing the criteria by incorporating limits in NPDES permits.

**Footnote:**

<sup>2</sup> See, for example, Gauthier, F. and Archibald, F. 2001. The ecology of "fecal indicator" bacteria commonly found in pulp and paper mill water systems. *Wat. Res.* 35(9) 2207-2218.; and Gauthier et. al. 2000. Coliform bacteria and nitrogen fixation in pulp and paper mill effluent treatment systems. *Applied Environmental Microbiology*. 66(12) 5155-5160.; and Tamplin, M.L. 2003. The application and suitability microbiological tests for fecal bacteria in pulp mill effluents: a review. *Water Qual. Res. J. Canada* 38(2) 221-225.

**Response:**

EPA recognizes there could be additional costs based the application of the water quality criteria in today's rule to waters with non-human sources of fecal contamination. However, sanitary surveys, in conjunction with scientifically defensible epidemiological studies, are necessary to ensure that the sources of the fecal contamination are non-human, and that the fecal contamination from those non-human sources does not pose a human health risk.

The commenters are correct that other indicators, not just fecal coliforms, have been found in pulp and paper effluent. However, *E. coli* and enterococci are less likely to be found in such effluent at elevated levels than fecal coliforms, thus making them better indicators of fecal contamination.

EPA Methods 1103.1, 1106.1, 1600, and 1603 have been subjected to interlaboratory validation in an assortment of disinfected wastewater matrices. The validation reports will for Methods 1600 and 1603 will be issued in late 2004, and in late 2005 for Methods 1103.1 and 1106.1. In addition, these methods will be modified for use in wastewater and will include all appropriate quality control parameters, and will be available at the same time as their respective validation reports. EPA did not specifically use pulp and paper effluent matrices in the study. Method validation studies typically include several representative matrices and are not intended to include every potential effluent matrix to which a method may be applicable.

## Issue: Non-Human Sources 4

**Organization Name:** American Society for Microbiology

**Document ID:** 162

**Comment ID:** 45

**Comment:**

The ASM offers the following recommendations in an effort to address some of the issues found in the proposed rule.

**ISSUE:** The proposed rule presents options for excluding or exempting from regulation nonhuman sources of fecal contamination. The most conservative option, excluding only wildlife sources, likely requires development and routine application of new methodologies for microbial indicator species and for microbial source tracking. Furthermore, because wildlife such as waterfowl harbor known human pathogens such as *Salmonella* spp. and *Campylobacter* spp., such fecal sources can not be ignored.

**SOLUTION:** The EPA should support a thorough evaluation of indicators that reliably reflect human livestock fecal contamination and methodological approaches that can distinguish wildlife contamination from other sources. Evaluations should also address the risks from wildlife fecal contamination.

**Response:**

EPA disagrees that including wildlife sources is the most conservative of the options for addressing non-human sources of pathogens in the rule, and did not select that option for the final rule. EPA agrees that more research in the area of risks from wildlife sources is warranted, and EPA is currently supporting efforts to determine sources of contamination. However, EPA would like to remind the commenter that microbial source tracking is a developing science and particular source tracking techniques have not been validated nationally.



## Issue: Non-Human Sources 5

**Organization Name:** Jeffrey A. MacDonald

**Document ID:** 177

**Comment ID:** 54

**Comment:**

**Issue -** "Do the Standards Exempt Fecal Contamination From Non-Human Sources?"

**Comment -** As is indicated in the proposed rule, "...high levels of these indicator organisms from animal sources may also indicate the presence of pathogens capable of causing other human illnesses in addition to acute gastroenteritis." It is entirely appropriate, and important to the protection of public health, that indicator organisms from animal sources fall within the scope of this rule.

However, *E. coli* that replicate in warm, nutrient rich environments *outside of a warm-blooded host* are not reflective of elevated public health risk. Bacterial source tracking using molecular methods (and other microbial methods, where appropriate) should be supported to determine the extent to which this phenomenon occurs.

**Organization Name:** Milwaukee Metropolitan Sewerage District

**Document ID:** 196

**Comment ID:** 190

**Comment:**

Issue: "Do the Standards **Exempt Fecal Contamination From Non-Human Sources?**" As is indicated in the proposed rule, "...high levels of these indicator organisms from animal sources may also indicate the presence of pathogens capable of causing other human illnesses in addition to acute gastroenteritis." It is entirely appropriate, and important to the protection of public health, that indicator organisms from animal sources fall within the scope of this rule. However, *E. coli* that replicate in warm, nutrient rich environments *outside of a warm-blooded host* are not reflective of elevated public health risk. Bacterial source tracking using molecular methods (and other microbial methods, where appropriate) should be supported to determine the extent to which this phenomenon occurs.

**Response:**

EPA acknowledges the comment that *E. coli* bacteria that replicate outside warm blooded hosts may not be reflective of elevated public health risk. However, the commenters did not provide information to support their comment, and thus EPA has no way to weight the accuracy of the comment. EPA's approach to addressing bacteria from non-human sources provides a means for addressing the situation presented by the comments. This approach allows States and Territories to demonstrate through sanitary and epidemiological studies that the indicators in a particular waterbody do not pose a risk to public health.

EPA disagrees that bacteria source tracking should be used as the means for determining the extent of the situation described in the comments. As discussed in section IV.V.7. of the preamble, EPA finds that the scientific understanding of these methods is still too incomplete to support promulgation of this approach.

## **Issue: Non-Human Sources 6**

**Organization Name:** Michael Doran Techknowledge

**Document ID:** 209

**Comment ID:** 151

**Comment:**

For certain waters it has been demonstrated that bacterial contamination is largely the result of non-human sources. Such contamination may have a lesser relative human illness risk than similar bacterial counts resulting from human sources. There is significant research being conducted at this time to develop testing procedures to quantify the sources of bacterial contamination and to allow their relative impact on the health of swimmers to be better determined. The following language is recommended to be added to the rule to allow the practical use of this information as it is developed: "As an alternative to the numeric standards contained in paragraphs (c)(1) and (c)(2), and providing that the risk of gastrointestinal symptoms to swimmers is maintained at or below 0.8% in fresh waters and 1.9% in marine waters, States may use different numeric standards for the bacterial species listed that are locally developed based upon source identification and epidemiologic analysis."

**Response:**

EPA disagrees that the rule should include the suggested regulatory language. As required by Clean Water Act section 303(i)(2)(A), EPA is promulgating its current section 304(a) criteria for pathogen and pathogen indicators (the 1986 bacteria criteria) for coastal recreation waters in states and territories that have not adopted criteria as protective of human health as EPA's criteria for coastal recreation waters. The rule does not constrain the flexibility that a state or territory has in using alternative methodologies for developing criteria, as long as the criteria that the state or territory develops is as protective of human health as EPA's 1986 bacteria criteria. Should a state or territory develop bacteria criteria chose to develop criteria that have different values than those in the 1986 bacteria criteria document but are as protective of human health as EPA's criteria, then EPA would consider the state's or territory's criteria sufficient under section 303(i) and would remove the applicability of the rule to that state or territory.

## Issue: Non-Human Sources 7

**Organization Name:** National Council for Air and Stream Improvement, Inc.

**Document ID:** 189

**Comment ID:** 40

### Comment:

The NCASI technical program has included the tracking and evaluation of bacterial indicator assays applied to pulp and paper effluents and receiving waters. Overall, this experience suggests that EPA should proceed with utmost caution as it implements alternative bacterial indicator assays to replace the fecal coliform indicator assay. Implementation of the new standards must recognize that positive indicator responses for both *E. coli* and enterococci assays can occur absent the presence of human fecal material. As such, implementation of the standards without attendant follow-up investigations may lead to burdensome restrictions on point and non-point sources with no related benefit to the protection of human health. The potential for this situation to occur, and suggested avenues to resolve such concerns, should appear more prominently in the proposal.

NCASI generally supports the use of *E. coli* and/or enterococci in place of fecal coliform as bacterial indicators of water quality because the former indicator bacteria can be more sensitive measures of fecal contamination. However, all these are indicator assays and numerous studies have shown that positive responses can occur absent human fecal contamination. In these circumstances, the indicator assay results may be invalid because the pathogens for which these assays are supposedly linked would not be present. In its question #4, EPA requests input on exemptions for cases where "...studies show the sources of the indicator bacteria to be nonhuman . . ." (69 FR 41729-31). Rather than limiting the exclusions to the three choices provided, EPA should allow states and dischargers broader latitude to demonstrate whether the health risks presumed by the presence of indicator bacteria are, or are unlikely to be, associated with the presence of human-borne pathogens. Such investigations, in addition to those noted by EPA, might include stream or source surveys, assays for select human pathogens, other assays indicative of the presence of sanitary waste, and use of modern techniques for tracing sources of microorganisms (e.g., pulsed-field gel electrophoresis, ribotyping, and multiple antibiotic resistance).<sup>1</sup>

**Footnote:** <sup>1</sup> Brief summaries of these techniques and bibliography are provided in Tamplin, M.L. 2003. The application and suitability microbiological tests for fecal bacteria in pulp mill effluents: a review. *Water Qual. Res. J. Canada* 38(2) 221-225.

### Response:

EPA recognizes that there will be instances where the ambient levels of either *E. coli* or enterococci will exceed the criterion but that the cause of the elevated concentrations may not be due to human fecal material. EPA notes, thought, that animal fecal material can contain human pathogens, as discussed in section IV.B.7. of the preamble. The rule in the footnotes to the criteria tables at 131.41(c) provide the means for a State or Territory to demonstrate that the source of the indicator is not human and that there is no risk to humans. If this is the case, then the rule allows the State or Territory to not apply the criteria to those indicator concentrations.

EPA has allowed States and Territories broad latitude to demonstrate that the indicators are not reflective of health risks to people exposed to the indicators. The rule in the footnotes to the criteria tables at 131.41(c) allows States and Territories to demonstrate through sanitary and epidemiological studies that the indicators in a particular waterbody do not pose a risk to public

health. EPA does not specify how a State or Territory would conduct the sanitary and epidemiological studies, only that the State or Territory can demonstrate that the source is not human and that there is no health risk from the source.

## Issue: Non-Human Sources 8

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 384

**Comment:**

We support not applying the criteria to a water body where the bacterial indicator is being exceeded due to natural conditions. Thus, we support a careful exclusion of wildlife; however, we do not support excluding pets and livestock. As EPA notes in its discussion the animals kept by humans are well documented as sources of major outbreaks - perhaps even more so than the point source discharges that are the focus of EPA's regulatory program on bacteria. The question that is not addressed is how to handle a wildlife exclusion. Though unquantified and certainly less than that of domesticated animals or people, fecal waste from wildlife - will create a risk to human health as well. The question in our view that needs to be addressed is how much, if any, additional degradation of the bacterial quality of the water should be allowed by human sources where wildlife alone cause an exceedence of the bacterial criteria. We certainly would support a minor increase that avoids having to assume zero human loading in TMDL or permit calculations, but not an approach that treats wildlife as having zero risk. We would suggest this approach should be restricted to the incremental range between the quantification level (representing a non-measurable increase) and the incremental increase associated with one addition illness rate (recognizing the use of the incidence curves developed by the EPA studies is better than picking a random number). This would produce a possible range for an incremental increase above natural (wildlife) levels of approximately 2-35/100 ml for *E. coli* in fresh water and 2-7/100 ml for enterococci in marine water.

**Response:**

Based on the available science, as described in the preamble to today's rule, in particular section IV.B.7., EPA is unable to determine how much less of a risk to human health wildlife poses absent scientifically defensible epidemiological data. For the reasons expressed in the preamble in section IV.B.7, EPA considers its approach necessary to be consistent with the requirements of the BEACH Act.

## Issue: Ohio

**Organization Name:** Northeast Ohio Regional Sewer District

**Document ID:** 198

**Comment ID:** 311

**Comment:**

**The State of Ohio's existing *E. coli* criteria are at least as protective as the Federal criteria.**

The proposed rule's preamble questions, in Section IV.B, the consistency of the State of Ohio's existing *E. coli* criteria with the Federal criteria because values equal to the SSM values are allowed in Ohio recreation waters to be exceeded in up to ten percent of samples collected during a thirty-day period.

However, as demonstrated in Attachment A, the difference in levels of protection under the proposed rule and the existing State of Ohio *E. coli* standards is inconsequential. Both significantly improve upon the goals used for development of the 1986 *Ambient Water Quality Criteria for Bacteria*. One advantage that the Ohio standards provide over the current proposal is summarized by EPA in the 1986 Criteria Document: "Increasing the number of samples improves the accuracy of bacterial water quality estimates, and also improves the likelihood of correct decisions on whether to close or leave open a beach." By replacing the SSM concept with statistically based concepts, the Ohio approach encourages increased sampling and is, in at least this respect, more protective than both the Federal criteria published in the Criteria Document and the proposed rule.

**Organization Name:** Northeast Ohio Regional Sewer District

**Document ID:** 198

**Comment ID:** 312

**Comment:**

Even further protection is afforded by the State of Ohio's designation of Lake Erie waters in their entirety as Bathing Waters rather than only so designating specific areas where heavy recreational use occurs (e.g., designated beach areas). Attainment of Bathing Waters recreational use standards is required by Ohio immediately outside the mixing zone of any point source of *E. coli* to Lake Erie, generally providing a "buffer zone" between the sources and the sites of heavy use. Although unnecessary, this additional layer of protection more than adequately compensates for the already inconsequential difference noted in Attachment A between the existing Ohio criteria and the proposed rule's interpretation of the SSM. The result is that, also in this respect, the existing Ohio criteria are more protective than both the Federal criteria and the proposed rule.

**Organization Name:** Northeast Ohio Regional Sewer District

**Document ID:** 198

**Comment ID:** 313

**Comment:**

Due to the above considerations, we emphatically assert that no change in the existing Ohio *E. coli* criteria is necessary for consistency with the Federal criteria, irrespective of which interpretation of the SSM is selected by EPA for the final rule.

**Organization Name:** Northeast Ohio Regional Sewer District

**Document ID:** 198

**Comment ID:** 472

**Comment:**

**Comparison of the Approaches**

The challenge to comparing the effectiveness of the disparate criteria is to arrive at a suitable data set for the comparison. In this case, the U.S. EPA Criteria documents provide a basis in the calculation of the SSM criteria. As noted above, these are based on the following parameters:

- Geometric Mean = 126 per 100 mL
- Standard Deviation, log10 basis = 0.4

A Monte Carlo run, based on these values, was used to generate a data set of 7,976 points. This data set is treated as daily samples for the remainder of this discussion.

Table 1 provides details of the data set before and after manipulations as specified below.

*Data Manipulation - U.S. EPA Criteria*

In order to mimic the conditions specified in the U.S. EPA Criteria, the data set was examined and each value over 235 per 100 mL was discarded. Not surprisingly, this resulted in a 25% reduction in the number of data points.

*Data Manipulation - OAC*

Creating a series that complies with Ohio standards was more complex since two separate, statistically based criteria are involved.

**Organization Name:** Northeast Ohio Regional Sewer District

**Document ID:** 198

**Comment ID:** 473

**Comment:**

To simulate the effects of the thirty-day limitation, a running geometric mean was calculated and, for each thirty-day period above 126 per 100 mL, the highest single value was removed. This was repeated until all thirty-day periods met the OAC criterion.

Once this was performed, each thirty-day period was examined for the number of values exceeding 235 per 100 mL. If there were more than three (10%), the lowest value greater than 235 per 100 mL was removed. This was repeated until no thirty-day period contained more than three values above 235 per 100 mL.

The lowest value was removed in the second operation to minimize the bias created by removing the highest value in the first step. The end result of these manipulations was nearly random data sets which conform to the various criteria. The results are summarized in Table 1 below.

TABLE 1  
SUMMARY OF DATA SETS

	"Raw" Monte Carlo Output	Per U.S.EPA Criteria	Per OAC 30- Day Geometric Mean Criterion	Per OAC Additional "No More than 10%" Criterion Geometric Mean
Geometric Mean	126	86	108	95
Standard Deviation, Log10 Basis	0.399	0.292	0.349	0.333
Number of Data Points	7976	6016	7209	6416
Estimated Number of Illnesses per 1,000 swimmers	8.00	6.44	7.37	6.85

Estimated illnesses based on regression equation presented in Health Effects Criteria for Fresh Recreational Waters. Fractional numbers shown to emphasize small differences involved.

**Organization Name:** Northeast Ohio Regional Sewer District

**Document ID:** 198

**Comment ID:** 474

**Comment:**

The stated goal of the U.S. EPA Criteria is an illness rate of no more than 8 per 1,000 swimmers. The criteria promulgated by the State of Ohio achieve and improve upon this goal. Further, the difference between the projected illness rates for U.S. EPA Criteria and OAC vary by less than 0.5 incidents per 1,000 swimmers. Given the uncertainties involved in both bacteria measurement and illness projection, this can only be considered to be insignificant. Therefore, the Ohio criteria are as protective of human health as the Federal standards.

**Organization Name:** Ohio EPA

**Document ID:** 206

**Comment ID:** 125

**Comment:**

I am responding on behalf of Ohio EPA to your request for information on the application of Ohio's bacteria water quality standards for Lake Erie. Ohio's water quality standards regulations for bacteria are in Chapter 3745-1 of the Ohio Administrative Code. The regulations include standards for both fecal coliform and *E. coli* bacteria. However, Ohio uses only the *E. coli* water quality standards for monitoring bacteria levels under the federal BEACH Act. The monitoring program is administered by the Ohio Department of Health (ODH).

The ODH beach monitoring program covers 22 popular beaches along Ohio's Lake Erie coast. ODH, along with certain county health departments, monitor *E. coli* levels and post beach advisories when warranted. Monitoring results are published on the ODH beach monitoring program Web site at <http://www.odh.state.oh.us/ODHPrograms/beach/sample.htm>. ODH uses Ohio's *E. coli* bathing water geometric mean standard of 126 colonies per 100 ml to make their decisions about posting beach advisories.

Ohio EPA's 2004 Integrated Water Quality Monitoring and Assessment Report incorporated the ODH Lake Erie beach data (*E. coli* data) into the assessment of water quality standards



attainment and Clean Water Act Section 303(d) listing. No fecal coliform data were used to assess water quality standards attainment of Lake Erie beaches. The report is available on-line at: <http://www.epa.state.oh.us/dsw/tmdl/2004IntReport/>.

I am confident the BEACH Act and Ohio's water quality standards regulations are applied the way they were intended.

**Organization Name:** State of Ohio Environmental Protection Agency

**Document ID:** 238

**Comment ID:** 127

**Comment:**

Ohio EPA appreciates the opportunity to comment on the proposed rule noticed in the Federal Register on July 9, 2004. Ohio EPA supports the level of water quality necessary to protect human health at the nation's coastal recreation areas, including Lake Erie. The *E. coli* criteria contained in the proposed rule have been codified in Ohio's water quality standards since 1990. Furthermore, the Ohio Department of Health conducts its beach bacteria monitoring and makes all beach posting decisions using the 1986 federal *E. coli* geometric mean criterion of 126 per 100 ml sample. This criterion is consistent with the BEACH Act requirements. Beach monitoring results and beach postings are available at the following Web address: <http://www.odh.state.oh.us/QDHProarams/BEACH/sample.htm>.

**Response:**

EPA has determined that Ohio's *E. coli* criteria, including its implementation of the single sample maximum, is as protective of human health as EPA's 1986 bacteria criteria. However, Ohio is included in the final rule because its water quality standards allow the use of either *E. coli* or fecal coliform and specify that compliance with the criteria can be demonstrated by attainment of either criterion. EPA is not aware of any data showing Ohio's fecal coliform criteria of 200/100ml for "bathing waters" to be as protective of human health as EPA's 1986 bacteria criteria.

EPA recognizes that some states regulate public bathing beaches through their Department of Health requirements. However, Section 303(i) of the Clean Water Act is clear that states must adopt recommended criteria into their water quality criteria and standards for coastal recreational waters that are as protective of human health as the EPA 1986 bacteria criteria. Moreover, States with BEACH Act implementation grants for monitoring and notification programs must use the applicable water quality standards, i.e., the water quality standards that protect the waterbody for swimming, bathing, surfing, or similar water contact activities.

Ohio EPA uses only *E. coli* data for assessing water quality in Lake Erie. However, as discussed in the preamble to the proposed rule, Ohio Water Quality Standards allow the use of either fecal coliform or *E. coli*, and specify that compliance with the criteria can be demonstrated by the attainment of either criterion (69 FR 41734). EPA does not consider the use of the fecal coliform criteria of 200/100ml to be as protective as human health as EPA's 1986 criteria.

EPA agrees that Ohio EPA requires attainment of the water quality standards at the edge of the mixing zones, and that this provides a "buffer" between sources and sites of heavy use. However, as the primary contact recreation use is designated at the edge of mixing zones, this does not appear to "more protective" than EPA's 1986 bacteria criteria. EPA does not see how the situation posed by the commenter provides additional protection for all primary recreation use.

The commenter who opined that Ohio's water quality standards result in more sampling did not explain the reason why there is increased sampling under the Ohio approach, nor does today's rule require a specific level of monitoring.

EPA notes that even if EPA agrees with the analysis provided by the commenter, that Ohio would still be included in the rule due to the fact that Ohio Water Quality Standards allow the use of either fecal coliform or *E. coli*, and specify that compliance with the criteria can be demonstrated by the attainment of either criterion. EPA does not consider the use of the fecal coliform criteria of 200/100ml to be as protective as human health as EPA's 1986 criteria. Should the Ohio EPA propose to remove the fecal coliform part of its criteria for recreational uses in Lake Erie, EPA would review the analysis by Ohio EPA and any commenters indicating that the upper bound criterion value in the Ohio water quality standards meets the requirements of Clean Water Act section 303(i).

## **Issue: Oregon**

**Organization Name:** Oregon Department of Environmental Quality

**Document ID:** 174

**Comment ID:** 56

### **Comment:**

EPA has not correctly characterized Oregon's rules regarding bacteria criteria. Oregon's freshwater criteria for bacteria are consistent with EPA's 1986 bacteria criteria; nevertheless, DEQ acknowledges EPA's decision to include Oregon in the proposed rule with regard to marine waters.

### **Response:**

EPA's characterization of Oregon's water quality standards, as expressed in the preamble of the proposed rule, reflects only the standards for waters subject to Clean Water Act section 303(i), that is, coastal recreation waters. EPA agrees that Oregon has adopted water quality criteria based on EPA's 1986 bacteria criteria for its inland and freshwater estuaries.

## Issue: Pennsylvania

**Organization Name:** Chesapeake Bay Foundation

**Document ID:** 231

**Comment ID:** 165

**Comment:**

CBF strongly supports the proposed policy for several compelling public health and welfare, environmental, and legal reasons. We believe that the proposed policy will result in greater environmental health for many coastal waters and the Great Lakes where impairment via pathogen contamination is significant. However, we believe that the proposal highlights many failings of Pennsylvania's pathogen monitoring and water quality standards which must be rectified. Our major concerns are set forth in detail below.

**Organization Name:** Chesapeake Bay Foundation

**Document ID:** 231

**Comment ID:** 166

**Comment:**

Pennsylvania's Outdated and Inaccurate Fecal Coliform Bacteria Criteria, and Its Failure To Adequacy List in Integrated ""303(d) and 305(b) List, Fails To Provide Adequate Notice To the Public of Pathogen Pollution. The proposed policy highlights deficiencies in Pennsylvania's efforts to restore and protect water quality and public health due to the way the Commonwealth measures and reports fecal contamination of its waters. Pennsylvania has an outdated and inaccurate system for notifying the public and protecting recreational water uses from fecal contamination. Notably, while Pennsylvania has approximately 1,600 Combined Sewer Overflows, thousands of livestock with direct access to surface waters, and a potentially significant number of failing septic systems (all known routes of routine pathogen contamination), which directly or indirectly enter waters that are used for various recreational uses, the Commonwealth fails to list any of these surface waters as impaired due to fecal contamination. Since neighboring states do list many waters for such impairment, it is either an incredible coincidence, or a tremendous oversight, that a minuscule number of waters in Pennsylvania are listed as impaired for fecal contamination on the Pennsylvania Department of Environmental Protection's recently proposed 2004 integrated"" 303(d)/305(b) list.

This issue is rooted in Pennsylvania's failure or refusal to update its bacteria criteria indicators to EPA standards. Pennsylvania is one of only a handful of states that has not adopted EPA's 1986 *E. Coli* or Enterococci Bacteria water quality criteria into its water quality standards. Instead, Pennsylvania retains an outdated and inaccurate fecal coliform indicator as an indicator of fecal contamination. As EPA acknowledges, fecal coliform criteria are correlated less strongly with swimming-associated gastroenteritis than other possible organisms [*E. coli* and enterococci], 68 Fed. Reg. 63049 (November 7, 2003).

Moreover, the Commonwealth has failed to adopt EPA's recommended instantaneous daily maximum value (IMAX) for *E. coli* that would provide a more comprehensive representation of the bacterial contamination of Pennsylvania waters. By restricting bacterial monitoring to a 5-day geometric mean, the state unreasonably narrows the scope of pathogen impaired waters in the Commonwealth. Pennsylvania is in Violation of Section 303(i)(1)(A) of the Clean Water Act.

Notably, Pennsylvania has also failed or refused to adopt EPA's Bacteria criteria indicators even though the state is required under the federal Beaches Environmental Assessment and Coastal

Health Act (BEACH) of 2000, as a state with waters bordering the Great Lakes, to adopt sufficient standards by April 10, 2004. Current state standards, which rely on fecal coliform counts, are obsolete and erroneous and are therefore insufficient.

**Organization Name:** Pennsylvania Department of Environmental Protection

**Document ID:** 233

**Comment ID:** 251

**Comment:**

In Pennsylvania, as in some other states, the Department of Health (PA DOH) has jurisdiction to regulate public bathing beaches, while water quality standards are the purview of the Department of Environmental Protection. The PA DOH has completed adoption of *E. coli* criteria consistent with EPA's recommended water quality criteria for bacteria) for public bathing beaches at 28 PA CODE, CH. 18, (related to Public Swimming and Bathing Places, by publication of final rulemaking in the Pennsylvania Bulletin on July 17, 2004 at 34 Pa.B. 3695.

**Organization Name:** Pennsylvania Department of Environmental Protection

**Document ID:** 233

**Comment ID:** 252

**Comment:**

While the federal BEACH Act applies to coastal beaches on the Great Lakes, including those at Presque Isle State Park in Erie County within the Commonwealth of Pennsylvania, the PA DOH final-form rulemaking extends the same level of protection to all public bathing beaches in the Commonwealth to provide a more effective and consistent level of public health protection to all individuals using any of the Commonwealth's bathing beaches. PA DOH is in the process of submitting these final-form regulations to EPA for review and approval, which we believe EPA will find to be consistent with the requirements of the federal BEACH Act.

Although we have maintained close communication with PA DOH and with EPA Region III, we still have no knowledge of if and how EPA's proposal would affect PA DEP's water quality standards program. All EPA correspondence relating to the Beaches Act requirements have gone only to the PA DOH. We specifically asked Region III to obtain an official response from EPA HQ, but have not received an answer.

While we fully expect that EPA's approval of the PA DOH regulations will remove this proposed promulgation for Pennsylvania, we are offering comments because of the implications that these beaches regulations will set a precedent for implementation of the bacteria criteria across all states and for other recreational waters not covered under the BEACH Act regulations. We are concerned about EPA's taking the bold and unusual step of including so many implementation issues in regulation.

**Response:**

Pennsylvania is included in today's rule because its water quality standards for its coastal recreation waters are not as protective of human health as EPA's 1986 bacteria criteria. Pennsylvania's inland waters are not included in today's rule because the scope of today's rule is limited to coastal recreation water, i.e., those marine and Great lakes waters designated for swimming, bathing, surfing, or similar water contact activities.

EPA is only promulgating criteria that are as protective of human health as the 1986 bacteria criteria, as required by the BEACH Act. EPA has not promulgated implementation procedures

with today's rule, but has illustrated approaches that States may use when implementing the criteria. In illustrating these approaches, EPA has attempted to provide information on key issues that the Agency also addressed in the draft implementation guidance. EPA intends to continue work on finalizing the Implementation Guidance to address those issues not contained in today's rule.

EPA recognizes that some states regulate public bathing beaches through their Department of Health requirements. However, Section 303(i) of the Clean Water Act is clear that states must adopt recommended criteria into their water quality criteria and standards for coastal recreational waters that are as protective of human health as the EPA 1986 bacteria criteria. Moreover, States with BEACH Act implementation grants for monitoring and notification programs must use the applicable water quality standards, i.e., the water quality standards that protect the waterbody for swimming, bathing, surfing, or similar water contact activities.

A representative from PA DEP has attended almost all of the meetings of the State/EPA Work Group on Water Quality Standards. EPA and the states established this group of co-regulators in 2001. The group has met two to three times a year since 2001. Because of continuing intense interest by state participants, the subject of bacteria criteria has been on the agenda for all of those meetings. The discussion has included both policy and technical matters. One or more senior managers from EPA have participated in every one of those discussions. Every state participant had full opportunity to raise issues, ask questions, and obtain information. For several meetings, EPA has brought its technical experts to the meetings to enable in-depth discussion of the criteria. In addition, the Work Group held several ad-hoc conference calls to continue the bacteria criteria discussions in more depth between meetings.

EPA appreciates the comments about the level of pathogens within the Commonwealth of Pennsylvania. However, this final rule applies to coastal recreation waters, as discussed in preamble to the final at section IV.A., Application of the Rule to Coastal Recreation Waters. Fresh waters designated as primary contact recreation (other than the Great Lakes) are not included in this final rule. States and Territories have discretion in designating waters for primary contact recreation; marine and Great Lakes waters designated by a State or Territory for primary recreation are considered coastal recreation waters.

EPA thanks the commenters who provided information on progress toward full compliance with the BEACH Act requirements.

## Issue: Presumption of Fishable/Swimmable

**Organization Name:** Kansas Department of Health and Environment, Division of Environment, Bureau of Water

**Document ID:** 173

**Comment ID:** 201

**Comment:**

*Which States and Territories Are Included in Today's Proposed Rule?* EPA states that no Tribes are included in the proposed rule because tribes have no "*coastal or Great Lakes waters designated for swimming, bathing, surfing or similar water contact activities.*" We presume the Tribes have not designated *any* uses for these waters, therefore a rebuttable presumption of swimming should prevail. In Kansas, EPA promulgated over 1,200 waters as primary contact recreation waters based on the concept of the rebuttable presumption that all waters must be designated for primary contact recreation unless proven otherwise. In the Kansas promulgation, EPA stated a "*rebuttable presumption of attainability, i.e., a default designation of CWA section 101(a) goal uses should apply.*" It seems inconsistent to apply the rebuttable presumption to some, but not all waters.

**Response:**

The 'rebuttable presumption of attainability' is a legal concept used when promulgating a designated use. EPA is not promulgating any designated uses in this rulemaking because section 303(i) of the Clean Water Act is directed at the adoption of water quality standards for pathogens and pathogen indicators only for coastal recreation waters, which are defined in part by whether the waterbody has already been designated for swimming, bathing, surfing, or similar water contact activities. EPA would review the appropriateness of designated uses at the time of water quality standards review.

## Issue: Public Notification

**Organization Name:** NRDC, Clean Water Project

**Document ID:** 192

**Comment ID:** 210

### **Comment:**

#### **Monitoring, Public Notification, and Beach Closures**

The BEACH Act was initiated to ensure that the CWA was responsive to the special environmental and health standards associated with recreational waters. To make these goals relevant, EPA's performance criteria must assure that public notification and other communication between levels of government occur whenever water quality standards are exceeded.

*The National Beach Guidance Performance Criteria*, states: "Advisories or closings, as appropriate, must be issued when indicator bacteria levels exceed the state or tribal water quality standard and there is not reason to doubt the accuracy of the sample." *National Beach Guidance Performance Criteria*, at 5.3.2. While the guidance is correct to mandate various reporting and notification requirements when "indicator bacteria levels exceed a water quality standard," the guidance also directs that "if there is reason to doubt" the accuracy of the sample, the relevant entity may resample before providing public notice. Compare *id.* at 5.1 with *id.* at 5.3.3. In fact, the guidance practically incorporates re-sampling (before notification) into the routine operation of the notification process. See, e.g., *id.* Table 4-2 at B. ("When a bacterial concentration exceeds a water quality standard, a state, tribe or local government must immediately either issue a public notification or resample.").

We note that at the local level, temptation to re-sample may be great, and we fear that a loose standard, without more specific guidelines as to when re-sampling may occur, will result in unreasonable delay in disseminating critical water quality information. We ask EPA to require notification whenever a water quality standard for bacteria is exceeded even if re-sampling will occur.

**Organization Name:** Surfrider Foundation

**Document ID:** 194

**Comment ID:** 120

### **Comment:**

#### **Use of the Single Sample Maximum (SSM)**

Second, we believe that it is appropriate to require, as a minimum, the posting of health advisories if either the SSM or the geometric mean is exceeded. In the case of an advisory based on exceedance of the SSM, the advisory would remain in effect until subsequent testing results were less than the SSM. This is the approach currently used by many jurisdictions, including California. We believe the decision to close beaches (as opposed to posting of advisories) is best left to the discretion of local or state health officials after consideration of additional factors, including evidence of sewer spills, weather, and additional testing results.



**Response:**

EPA appreciates the comments; however, the National Beach Guidance and Required Performance Criteria for Grants and comments related to suggested requirements for beach monitoring and notification programs are outside the scope of the rule.

## Issue: Recreation Categories

**Organization Name:** Buckeye Florida

**Document ID:** 172

**Comment ID:** 236

**Comment:**

*Definition of Coastal Recreation Waters* - Using the geometric mean only approach for water quality criteria and the SSMs for public health guidance eliminates the need for EPA established definitions.

**Organization Name:** Buckeye Florida

**Document ID:** 172

**Comment ID:** 237

**Comment:**

*State Identification of Coastal Recreation Waters by Category* - Again, the use of the geometric mean only approach for water quality criteria and the SSMs for public health guidance eliminates the need for rigid State identification of recreation waters by category.

**Organization Name:** California Regional Water Quality Control Board

**Document ID:** 203

**Comment ID:** 99

**Comment:**

### **Alternative Options for Categorization of Coastal Recreation Waters**

"EPA is also considering an approach where the SSM is not part of the criterion, but rather part of the water quality standards implementation process."

The Regional Board believes that SSMs must remain a part of the criteria, not merely as part of the water quality standards implementation process.

As previously discussed the main point of opposition to SSMs as part of water quality standards seems to be the high day-to-day variability of bacteria densities in single samples. The exceedance of SSM-based standards due to bacteria loading from natural sources is also a concern. The Los Angeles Regional Board has developed an alternative implementation process that addresses both of these concerns by allowing a certain frequency of exceedance of the SSM standard due to bacteria loading from natural sources. The reference beach approach was approved by the USEPA, Region IX and has been used by the Los Angeles Regional Board in TMDL development, including the *Santa Monica Bay Beaches Dry-Weather and Wet-Weather Bacteria TMDLs*. These TMDLs "permit a certain number of daily exceedances of the single sample maximum objectives. This approach recognizes that there are natural sources of bacteria that may cause or contribute to exceedances of the single sample objective." TMDLs based on this approach require that bacteria loading to urbanized beaches/watersheds be reduced to levels of the reference beach/watershed. The reference beach/watershed approach ensures that water quality at other monitored shoreline locations is at least as good as the reference beach/watershed of an undeveloped area. The San Diego Regional Board is proposing similar implementation provisions for its bacteria objectives.

**Organization Name:** California Regional Water Quality Control Board, San Diego Region  
**Document ID:** 199  
**Comment ID:** 117

**Comment:**

**Alternative Options for Categorization of Coastal Recreation Waters**

"...EPA is also considering an approach where the SSM is not part of the criterion, but rather part of the water quality standards implementation process..."

The Regional Board believes that SSMs must remain a part of the criteria, not as part of the water quality standards implementation process.

As previously discussed, the main point of opposition to SSMs as part of water quality standards seems to be the high day-to-day variability of bacteria densities in single samples. The exceedance of SSM-based standards due to bacteria loading from natural sources is also a concern. An alternative implementation process that addresses both of these concerns, already developed by the California Regional Water Quality Control Board, Los Angeles Region and proposed as a basin plan amendment to the San Diego Region Basin Plan, allows a certain frequency of exceedance of the SSM standard due to bacteria loading from natural sources. The reference beach approach, developed by the Los Angeles Regional Board in its EPA-approved *Santa Monica Bay Beaches Wet-Weather Bacteria TMDL*, "permit[s] a certain number of daily exceedances of the single sample maximum objectives. This approach recognizes that there are natural sources of bacteria that may cause or contribute to exceedances of the single sample objective." TMDLs based on this approach require that bacteria loading in urbanized beaches/watersheds be reduced to levels of the reference beach/watershed. The reference beach/watershed approach ensures that water quality at other monitored shoreline locations is at least as good as the reference beach/watershed fed from an undeveloped area. Further, the development of the reference beach exceedance frequency would incorporate the daily variability of single samples. In other words, some of the exceedances measured in the reference watershed would be due to high loading from natural sources, and some due to samples collected in unrepresentative high density zones.

**Organization Name:** California Stormwater Quality Association  
**Document ID:** 202  
**Comment ID:** 132

**Comment:**

**Issue:** Delineation of Coastal Recreation Water Uses

USEPA is considering and has proposed different categories of coastal recreation water uses. The four categories include: (1) Designated bathing beaches; (2) Moderate use coastal recreation waters; (3) Light use coastal recreation waters; and (4) Infrequent use coastal recreation waters. CASQA supports in concept the use of multiple categories of recreation water uses, although we question the practicality of varying SSMs for the categories. The wide range of bacterial densities associated with the surf zone make the relatively small range of SSM values somewhat academic regarding compliance and attainment.

**Organization Name:** Department of Environmental Services City and County of Honolulu  
**Document ID:** 235  
**Comment ID:** 299

**Comment:**

Section 131.41(c)(2)

If single sample maximums are to be included in the WQS, coastal recreation waters should be categorized based on usage and not on the presence of a lifeguard, parking lot, public access, etc. We suggest a peak usage density figure (no. of users/per square mile) be used. For Hawaii, the peak usage densities could be determined as part of the beach user study proposed to be done jointly with State DOH and other counties.

**Organization Name:** Florida Department of Health

**Document ID:** 230

**Comment ID:** 475

**Comment:**

At this time, we plan to continue to use the 35 geomean and 104 SSM criteria, and will not use the four separate use categories.

**Organization Name:** Jeffrey A. MacDonald

**Document ID:** 177

**Comment ID:** 51

**Comment:**

Use designation of water bodies (or portions thereof). The proposed rule identifies 4 categories of coastal recreation waters; designated bathing beaches, moderate use coastal recreation, light use coastal recreation waters, and infrequent use coastal recreation.

These use designations are quite vague. No mention is made of use designation relative to sources of drinking water. Particularly on the Great Lakes, many communities draw drinking water from, and discharge treated wastewater effluent into, the same water body. Guidance is needed on determining use designation and proximity of effluent outfalls to drinking water intakes. If Use Attainability Analyses or other tools are required of NPDES holders in order to define water use, the rule should contain very specific guidance regarding the performance of such actions. It is important to have provision in the rule that will place wastewater effluent outfalls in a category such as infrequent use coastal recreation (or a less restrictive category), when appropriate.

**Organization Name:** Jeffrey A. MacDonald

**Document ID:** 177

**Comment ID:** 53

**Comment:**

**Issue -** "EPA is considering promulgating only the 75 percent confidence level SSM..."

**Comment -** Using the 1% risk level, the SSM (listed on p. 41725 of the proposed rule) is 385 *E. coli* 100 mL. Use of a SSM to regulate the NPDES community is inappropriate, and is strongly discouraged (see issue 3 of this document regarding the inappropriateness of using SSMs for regulating wastewater dischargers). Application of one standard to all entities, with no regard for differences in physical layout, hydrological regime, variation in inputs, or other variables is considered inappropriate and is strongly discouraged.

**Organization Name:** King County Department of Natural Resources and Parks

**Document ID:** 204

**Comment ID:** 329

**Comment:**

The definition of the effected areas (high use-low use) could create significant confusion. As we will note in other comments below, requiring the state to distinguish small segments of coastal waters as "high or infrequent use" is not as straight forward in this part of the country as it perhaps may be in other areas.

**Organization Name:** King County Department of Natural Resources and Parks

**Document ID:** 204

**Comment ID:** 336

**Comment:**

The proposal focuses on Single Sample Maximums (SSM) values described as appropriate to 'high to infrequent use' areas. This does not address the differing nature of recreational uses through out the country or the differences in the nature of wet-weather conditions that are experienced. The Pacific Northwest does not typically have wet weather conditions during the summer period when swimming would be expected. However in the fall and winter during wet weather there are times when there is kayaking, and other boating sports which while offering some opportunity for exposure to bacteria, offers much less opportunity for water ingestion than the full head-immersion that swimming will allow. The one full immersion sport that is practiced in this region in the wetter periods is scuba diving but only in specific localized areas. These differences in recreational activities and their differing potential for disease risk must be taken into account when determining that a standard be used based solely on research focusing on ingestion.

**Organization Name:** King County Department of Natural Resources and Parks

**Document ID:** 204

**Comment ID:** 337

**Comment:**

Regarding EPA's announcement requested comments on the SSMs proposed, we strongly urge EPA not to impose only one SSM - the 75% CL standard. For all the reasons of variability in natural flow and source conditions described above, we feel applying that SSM would be inappropriate and would create instances of where the standard is periodically exceeded where no heightened health risk actually exists. We would suggest, if a enterococcus standard is to be applied that either no SSM accompany the geometric mean or an approach be considered that looks at the highest 10% of the samples, measured rather than a single exceedance standard. With their great potential for being exceeded by the natural variability, use of SSMs would not help target priorities for improving water quality. It could potentially list so many more sites, causing greater difficulty in focusing scarce funding for accomplishing TMDLs and clean-up plans.

**Organization Name:** Louisiana Department of Environmental Quality

**Document ID:** 169

**Comment ID:** 315

**Comment:**

As outlined in previous letters to EPA, Louisiana's coastline is estimated to encompass 7,721 miles, but there are few beaches that come close to EPA's proposed definition of 'designated

bathing beach waters' or the 'high use, designated beach areas' described in the EPA guidance (i.e., lifeguard-protected, parking provided, publicly accessed, and heavily used). Of the total miles of Louisiana's coastline, 23.18 miles have been identified and assigned to a monitoring tier through Louisiana's Beach Monitoring Program managed by the Louisiana Department of Health and Hospitals (LDHH). This program is funded by EPA as part of the CWA at 406 BEACH Act grant made available to states beginning in 1999-2000.

In summary, LDHH used a systematic process to identify and rank Louisiana's beaches according to risk, and provides the results of that evaluation in the report. The analysis included: 1) the identification and definition of coastal recreation waters; 2) identification of Louisiana beaches; 3) review of available information on potential fecal pollution; 4) beach use intensity; and 5) rankings to prioritize those beaches to be included in Louisiana's Beach Monitoring program. Sampling, monitoring, and public notification has been fully implemented at three pilot study beaches and will be expanded to all of the Tier 1 - Tier 3 beaches by the end of 2005.

**Organization Name:** Louisiana Department of Environmental Quality

**Document ID:** 169

**Comment ID:** 316

**Comment:**

**The LDHH BEACH Monitoring Program results and the LDHH Louisiana's BEACH Grant Report FY 2001 should be used to identify Louisiana's coastal recreation waters and beaches consistent with the BEACH Act.**

Louisiana has been developing a monitoring program for coastal recreation beaches since the BEACH Act became effective during 2000. Under the Clean Water Act (CWA) at 406, the Louisiana Department of Health and Hospitals (LDHH) was the recipient of a grant from EPA Region 6 to develop and implement Louisiana's Beach Monitoring Program in accordance with EPA's Program Performance Criteria. The LDHH also recognized that the implementation of Louisiana's Beach Monitoring Program would be further enhanced by collaboration with the Louisiana Office of State Parks and Historic Sites (OSP). LDEQ was consulted for water quality data and technical guidance, and the Lake Pontchartrain Basin Foundation (LPBF) is also partner on monitoring efforts in Lake Pontchartrain.

Louisiana's Beach Monitoring Program and methodology is documented in the LDHH report entitled, "*Louisiana's BEACH Grant Final Report Grant Year 2001*", which was completed and submitted to EPA during the summer of 2003. The report was also public noticed in the Potpourri section of the *Louisiana Register*, the state's official medium for making administrative law documents public. In this report, LDEQ's Water Quality Management Basin subsegments (see LAC 33:IX.1123.A) were used as the basis, along with other decision criteria, to identify Louisiana's "coastal recreation waters" which are listed in Appendix 1 ([www.ophbeachmonitoring.com](http://www.ophbeachmonitoring.com)). These subsegments are currently designated in the Water Quality Standards for primary and secondary contact recreation uses. Primary contact criteria apply during the recreational period of May 1 through October 31.<sup>1</sup>

**Coastal Recreation Waters:**

Based on the information in the LDHH report, and consistent with EPA guidance, LDEQ considers a designated use for 'Coastal Recreation' as:  
"any recreational use in coastal waters (as defined by LDEQ and LDHH) of limited accessibility and low swimmer incidence, and in which full-body water contact is infrequent."

As previously recommended to LDEQ by EPA, criteria densities would be as those applied to marine waters (enterococci) for 'infrequently used, full body contact recreation (upper 95% C.L.) or 501', (*Bacteriological Ambient Water Quality Criteria for Marine and Fresh Recreational Waters*, EPA, 1986).

**Footnote:**

<sup>1</sup> A map of the coastal recreation waters for BEACH Act purposes is included as Figure 2.1 in the report.

**Organization Name:** Louisiana Department of Environmental Quality

**Document ID:** 169

**Comment ID:** 320

**Comment:**

**Identifying "bathing beach waters" in Louisiana:**

The "coastal recreational waters" as identified in the LDHH report were expansively examined to determine if beaches or similar points of access used by the public for swimming, bathing, surfing, or similar water contact activities were present during the recreational period. A definition for 'beach' is currently not included in Louisiana's Water Quality Standards (LAC 33:IX.1111). However, the Louisiana Public Health Sanitary Code (LAC 52:XXIV) contains definitions for "natural swimming place or bathing place" and "semi-artificial swimming pool or bathing place or bathing beach". For Louisiana Beach Monitoring Program purposes, "bathing beach" was defined as any area within Louisiana's coastal recreation waters that is regularly used by the public for swimming, recreational bathing, sporting events, therapeutic treatment, ceremonies, or any other related activities in which people are immersed. To further identify the subset of beaches within the "coastal recreational waters", parish sheriff's offices were contacted to identify the areas that could be described as a "bathing beach". A BEACH survey Form was developed using EPA's guidance and is contained in Appendix 2 of the LDHH report.<sup>2</sup> The Lake Pontchartrain Basin Foundation also provided information about current and potential beach sites at Lake Pontchartrain. Currently and potentially used beaches in Louisiana within each parish are listed and a map of their locations is provided in Table 2.1 and Figure 2.2, respectively, of the LDHH report.

**Footnotes:**

<sup>2</sup> Survey responses were summarized and are part of the Administrative Record, available at LDHH offices

**Organization Name:** Louisiana Department of Environmental Quality

**Document ID:** 169

**Comment ID:** 321

**Comment:**

**"Bathing Beaches" Intensity of Use.** In total, 25 potential Louisiana beaches were identified and delineated on digital aerial photography in a geographic information systems format (GIS).<sup>3</sup> Composites of all aerial photographs are available at LDHH offices and are considered part of LDHH Administrative Record.

Since precise numbers of Louisiana beach visitors are not available, law enforcement officials and park managers responsible for patrolling the beaches were surveyed and provided estimates

of beach visitors and a percentage of beach users entering the water on a typical weekday, weekend, and holiday during the peak swimming season.

The total recreational period use was calculated (these are not estimates of swimmers at any one time), and five broad categories of use are listed below:

<u>Category of Use</u>	<u>Estimated Number of Swimmers</u>
Very Low	<5,000
Low	5,000 to <10,000
Moderate	10,000 to <15,000
High	15,000 to 20,000
Very High	>20,000

**Risk Based Rankings.** Because water quality in Louisiana is assessed for 305(b) purposes at the water body or subsegment level by LDEQ, identified beaches were aggregated into seven basin areas and beach specific information assessed within each basin area (Lake Pontchartrain Basin, Barataria Basin, Vermilion-Teche River Basin, Calcasieu River Basin-Lake Charles Beaches, Calcasieu River Basin-Cameron Beaches, Mermentau River Basin, and Sabine River Basin). The BEACH Act program is designed to limit the risk of the swimming public from contracting human pathogens that cause gastrointestinal illness. Ideally, a risk-based ranking of beaches should be based on the estimated number of individuals likely to contract a gastrointestinal illness as a direct result of primary contact recreation at the beach. To accomplish this in a quantitative fashion for each beach, estimates of known precision of the concentration of indicator organisms, the likelihood of contracting an illness if exposed to waters with a specified indicator organism concentration, and the number of beach users that engage in primary contact recreation must be available. At this point, none of these factors are known precisely. Beach water quality is either inferred from the water quality of the area as a whole, or based on a short period of data. No studies are currently available that provide a site-specific relationship for Louisiana's beaches.

**Footnote:**

<sup>3</sup> For the well-established beaches less than one-half mile long, the entire beach was delineated. For longer beaches, aerial photographs were taken during Memorial Day weekend (Saturday, May 26, 2002), because local officials had identified this holiday as one of the most heavily used periods of the year. Photographs were taken between 11:00 a.m. and 4:00 p.m., typically the period of heaviest use during the day. Occupied areas were then delineated.

**Organization Name:** Louisiana Department of Environmental Quality

**Document ID:** 169

**Comment ID:** 322

**Comment:**

However, in the interim (until site-specific, risk-based studies are completed), LDHH has developed a risk-based ranking for Louisiana's coastal beaches largely based on estimated numbers of swimmers (swimmer density) and water quality at each beach. Once states have developed such a ranking of their beaches, EPA recommends development and implementation of a three-tiered monitoring plan<sup>4</sup> which documents where to collect samples, when to conduct basic and additional sampling, and what depth to sample. The tiers of the monitoring plan can provide



different intensities of monitoring best applied to a beach segment. Some beaches were excluded from ranking due to their locations on private property, very low and low use, or an advisory against swimming. If these conditions change at these beaches, their classification could change as part of the annual review process of beach rankings. Accordingly, each LDHH ranked beach was assigned to a monitoring tier. A total of 29.16 miles of beach were ultimately considered for monitoring under the Louisiana BEACH Monitoring Program, of which 23.18 miles have been ranked and assigned to a monitoring tier.

### **Louisiana's "Bathing Beach Waters."**

Tier 1 (very high, high, or moderate to high use) = 8.25 miles

Fontainebleau State Park (Lake Pontchartrain Basin)

Grand Isle State Park (Barataria Basin)

Fourchon Beach (Barataria Basin)

Cypremort Point State Park (Vermilion-Teche River Basin)

North, South, and Rabbit Island Beaches (Calcasieu River Basin-Lake Charles)

Holly Beach (Calcasieu River Basin-Cameron)

Tier 2 (moderate use) = 12.53 miles

Grand Isle Beach (Barataria Basin)

Constance Beach Complex (Sabine River Basin)

Tier 3 (low or very low use and insufficient data to rank) = 2.40 miles

Hackberry Beach (Mermentau River Basin)

Rutherford Beach (Mermentau River Basin)

Sampling locations (see Table 3.1 of the report) were selected for each beach based on the aerial photography of documented beach use during the Memorial Day weekend (see Footnote 3). Sanitary surveys were also conducted in accordance with EPA guidance to identify any known or potential sources of fecal contamination affecting the beaches.

The Louisiana Beach Monitoring Program uses two indicator organisms to assess beach water quality, fecal coliform and enterococci. Fecal coliform is the primary indicator organism currently used as the standard to assess bacteriological water quality for the "bathing beaches/places" by LDHH (LAC 51:XXIV at 909.B) and to assess whether a water body's designated use in LDEQ's Water Quality Standards (LAC 33:IX. AT1113.C.5), is being met. Enterococci are EPA's recommended indicator organism for monitoring marine recreational waters and will be used by the LDHH Beach Monitoring program in addition to fecal coliform.

### **Footnotes:**

<sup>4</sup> *National Beach Guidance and Performance Criteria for Grants*. June 2002. USEPA 823/B-02-004. U.S. Environmental Protection Agency, Office of Water, Washington, DC.

**Organization Name:** Massachusetts Department of Environmental Protection

**Document ID:** 208

**Comment ID:** 476

### **Comment:**

There should be different categories of waters depending on frequency of use and whether there is an official beach involved.

**Organization Name:** Milwaukee Metropolitan Sewerage District

**Document ID:** 196

**Comment ID:** 186

**Comment:**

Regarding proposed **definitions for each category of waterbody**: With the exception of the "designated bathing beach waters" category, the definitions are too vague to be meaningful. No mention is made of use designation relative to sources of drinking water. Particularly on the Great Lakes, many communities draw drinking water from, and discharge treated wastewater effluent into, the same water body. Guidance is needed on determining use designation and proximity of effluent outfalls to drinking water intakes. It is important to have a provision in the rule that will place wastewater effluent outfalls in a category such as infrequent use coastal recreation (or a less restrictive category), when appropriate.

**Organization Name:** NRDC, Clean Water Project

**Document ID:** 192

**Comment ID:** 205

**Comment:**

**Single Sample Maximum Criteria**

The EPA proposes to implement the agency's 304(a) criteria for the single sample maximum (SSM) number by defining the following terms: designated beach waters; moderate use coastal recreation waters; light use coastal recreation waters; and infrequent use coastal recreation waters. EPA then proposes SSM criteria based on confidence level numbers for each subcategory of recreational waters consistent with the 1986 criteria. The SSM confidence level numbers are based upon statistical correlations between the SSM numbers and violation of the applicable geometric mean criteria. These numbers are 75%; 82%; 90%; and 95%, and correlate respectively with the designated beach waters; moderate use waters; light use waters; and infrequent use waters.

The EPA proposed rule suggests multiple alternatives to the preferred alternative outlined above. NRDC endorses the following alternative proposal outlined by the US EPA in the proposed rule: "EPA is also considering promulgating only the 75 percent confidence level SSM that would apply to all coastal recreation waters of the States and Territories included in the final rulemaking. This approach applies the most stringent SSM to all coastal recreation waters and is thus more protective than the 1986 bacteria criteria. However, it also simplifies the application of the standards by eliminating the need to delineate which SSM applies to specific coastal recreation waters." 69 Fed. Reg. at 41726.

NRDC strongly supports this option. EPA identified the 75% confidence interval as the most appropriate number to rely on for making beach closure and public notification decisions in the agency's June 2003 draft document, *Implementation Guidance for Ambient Water Quality Criteria for Bacteria*. The EPA Office of Water recently endorsed these recommendations in its: *Recreational Beach Monitoring Guidance - Recreational Beach Monitoring Guidance - Issues and Recommendations: a review of current EPA monitoring recommendations and recent studies* (including ORD EMPACT Beaches Project), December 2003 Draft.

In summary, while the geometric mean number is an appropriate standard to continue to use, along with an appropriate SSM number or numbers, in making use support decisions, EPA's more current science recommends that the EPA and the states use the 75% confidence interval number

as the primary criterion for beach advisory and closure decisions. The 75% SSM number is more protective than the EPA's proposed approach; simpler to implement and enforce; and represents the most scientifically defensible criterion. EPA should not allow itself to become "locked into" its 1986 criteria document where subsequent research and science support the promulgation of more stringent criteria.

**Organization Name:** New Jersey Department of Environmental Protection

**Document ID:** 178

**Comment ID:** 21

**Comment:**

**Categories of Coastal Recreation Waters**

New Jersey agrees with the 1986 Criteria that one size does not fit all and that it is reasonable to assign primary contact use designations based on use intensity. New Jersey also believes that EPA should provide some definition and examples of moderate, light, and low intensity uses for use as guidance for implementation purposes.

**Organization Name:** New Jersey Department of Environmental Protection

**Document ID:** 178

**Comment ID:** 23

**Comment:**

**Categorization of Coastal Recreation Waters**

There should be no more than one SSM value for beach closure decisions. The value employed should continue to be the 75<sup>th</sup> upper confidence interval (CI) value as it is the most conservative (safest) of the four established upper CI values. For coastal recreational waters not classified as public beaches and subject to beach closures, all assessment should be based on a Gm. From this, it follows that no "use intensity definitions" based on SSM (p. 41725) are needed and there is no need to distinguish intrastate and interstate use intensities (p. 41727).

For locations with insufficient data to calculate a valid Gm, compliance with any SSM value offers no guarantee that a waterbody will or will not have an acceptable Gm. Even when using the most "liberal" 95% upper CI value, 5% of the data from a water body having a Gm equivalent to the acceptable Gm will be above the SSM value. A reasonable compromise to establish acceptable water quality in such situations is to extend the 30 day period in which the 5 or more samples can be collected. However, this should be permitted only when there is a "reasonable certainty" that pollution sources and inputs during the extended period are not significantly different than during the first 30 days of that period.

Single sample maximum values are arbitrary values. No scientifically-based reasoning or process was used to select the four upper confidence interval values specified in the 1986 criteria. One can calculate any upper confidence interval one chooses about a specified set of data. Thus, it is not "reasonable to have different SSMs depending on use intensity" (last sentence of p. 71726). If anything, this practice should be prohibited. Water quality assessment decisions should be based solely on the Gm value. The use of SSM values to establish "acceptability" of a waterbody where there is enough data to calculate a valid Gm is highly questionable.

Allowing the use of different SSM values to establish "acceptability" at separate waterbodies, in lieu of sufficient data to allow a valid Gm calculation at those sites, should be prohibited rather

than encouraged. Within this context, employing different SSMs at separate waterbodies is no different than setting different Gm values (*i.e.*, illness risk levels) at those waterbodies.

**Organization Name:** New York State Department of Environmental Conservation

**Document ID:** 218

**Comment ID:** 86

**Comment:**

Categorization of Coastal Recreation Waters: Single Sample Maximums.

We request that the final rule for New York include only one single sample maximum (SSM) - the most protective (75 percent confidence level) SSM, for all coastal fresh and marine waters with the designated best use of primary contact recreation. This provides the greatest protection as well as the greatest consistency across all such waters, regardless of the current level of use of a particular beach. The options that the USEPA has suggested where beaches with different frequencies of public use would offer different levels of health protection, is complex and difficult to implement, and appears inherently unfair to those persons who choose to swim at a less crowded beach. We believe that strong and equal protection should be provided to all users of New York's waters that are designated for primary contact recreation.

**Organization Name:** Oregon Department of Environmental Quality

**Document ID:** 174

**Comment ID:** 63

**Comment:**

EPA is considering applying the "designated bathing beach" single sample maximum to all waters of states' DEQ believes little or no reduction in public health risks would be gained and potentially large socioeconomic costs would occur if EPA were to finalize this option. None of Oregon's marine beaches fit the description of "designated bathing beach" and therefore, it would be inappropriate for EPA's final rule to force Oregon to spend scarce resources on a problem that does not exist.

**Organization Name:** Oregon Department of Environmental Quality

**Document ID:** 174

**Comment ID:** 65

**Comment:**

EPA should develop guidance on how to designate bathing beaches. Such guidance should explain the specific densities of bathers used for different categories of uses and should consider additional data from epidemiological studies at the low use densities typical of Oregon and some other states (if such data exist). Oregon does not have much information on the level of beach usage that could be used in defining the categories under single sample maximums.

**Organization Name:** Pennsylvania Department of Environmental Protection

**Document ID:** 233

**Comment ID:** 485

**Comment:**

The adoption of only a geometric mean obviates the need for the tenuous decision about classification of waters, other than permitted beaches, used to varying degrees by swimmers. We believe that the highest level of protection is appropriate for permitted beaches, and because that

is the focus of the regulations, there is no need to "force" the definition of other levels of use into additional SSMs.

**Organization Name:** South Carolina Department of Health and Environmental Control Bureau of Water

**Document ID:** 161

**Comment ID:** 220

**Comment:**

**Issue:** Possible contravention of antibacksliding.

How is it possible for EPA to "interpret" the phrase "as protective of human health as" the 1986 criteria by only requiring an SSM for designated bathing beach areas? This would not incorporate the existing use classification and applicable values currently being used by the states with fecal coliform values and therefore, would possibly contravene antibacksliding requirements.

**Organization Name:** South Carolina Department of Health and Environmental Control Bureau of Water

**Document ID:** 161

**Comment ID:** 224

**Comment:**

**Use of scientifically credible sources of data and information.**

The EPA must maintain its reputation for using the best science available when recommending its criteria to the nation. This notice includes a section regarding how frequency determinations could be defined. The sources listed in the notice of how that recommendation was determined by the EPA is simply not up to a scientifically-defensible level and the EPA should withdraw its recommendations.

**Organization Name:** State of Alaska Department of Environmental Conservation/Division of Water

**Document ID:** 175

**Comment ID:** 155

**Comment:**

**Categories of Coastal Recreation Waters.**

The State of Alaska supports the EPA proposal not to list individual waters by intensity of use category, leaving use intensity determinations to individual CWA actions. We strongly object to options for categorizing use intensity that would eliminate very infrequent use and low risk designations that could result in protecting vast stretches of Alaska's water for a level of use intensity that simply does not exist.

**Organization Name:** State of Alaska Department of Environmental Conservation/Division of Water

**Document ID:** 175

**Comment ID:** 159

**Comment:**

Contact recreational use of Alaska's coastal waters is unlike that of any other state or territory. Conditions such as the absence of sunlight for months at a time or the presence of pack ice simply are not conducive to a refreshing dip in the ocean. All waters along Alaska's 36,000 miles of coastline are protected for contact recreational use, though such use rarely is that of the traditional bathing beaches found in other states. Any rule designed primarily with intensive traditional bathing beach use in mind runs a risk of regulatory absurdity when viewed from the perspective of the actual nature and intensity of contact recreational use of Alaska's coastal waters. Our comments are intended to assist EPA in crafting a final rule that will work for the 54% of U.S. coastal waters that are found in Alaska.

**Organization Name:** State of Connecticut Department of Environmental Protection

**Document ID:** 244

**Comment ID:** 162

**Comment:**

EPA also solicited comment on its proposal to objectively define four categories of intensity of use and allow states to apply these categories at the time CWA actions are taken. Connecticut strongly endorses this approach. The proposed approach will facilitate states' establishing "tiers" of recreational use based on intensity of use. Coupling this process with other CWA actions, such as NPDES permit issuance or establishing TMDLs, will provide ample opportunity for public input to this process. This is the approach Connecticut has used in implementing the 1986 criteria and has found it to be workable. The alternatives, establishing the use intensity level for all recreational waters *a priori* or assuming that all waters are high intensity use waters absent a UAA to "downgrade" the use, are administratively burdensome and wholly unacceptable.

**Organization Name:** State of Hawaii Department of Health/Environmental Health Administration

**Document ID:** 195

**Comment ID:** 398

**Comment:**

**The State's Preferred Options**

Given the options available in EPA's proposed rule, we recommend that only two tiers of beaches along with only two SSMs be incorporated into the final federal rule for Hawaii. (We believe that other states' preferences for their waters should be accommodated.) Two tiers will simplify the distinctions between the four proposed tiers and concentrate on protecting beaches that receive the highest use. The two tiers of beaches would both be within the State's present 300 meter/1000 foot marine recreational waters boundary (HAR sec. 11-54-08(b)).

For the two tiers of beaches, DOH recommends only two corresponding single sample maxima (SSMs) within Hawaii's existing 300 meter/1000-ft nearshore marine recreational waters boundary in order to simplify the classifications and maximize our efforts to protect the Tier 1 - Designated Beaches (primary protection) and Tier 2 - Other Beaches (secondary protection).

**1. Beach Tiers:**

a. Tier 1 - Designated Beaches, are defined as having the following characteristics - they are heavily used by the public for full body-contact recreation (bathing), and may be lifeguard

protected, have parking and other public facilities. The DOH would develop a list of designated beaches.

b. Tier 2 - Other Beaches, are beaches that are not Designated Beaches. They have the following characteristics - moderate use for bathing, light use for bathing, and infrequent use for bathing.

## **2. Beach Tiers, Open Coastal and Oceanic Waters, and SSMs:**

Within 300 meters/1000 feet of shore:

a. For Tier 1- Designated Beaches, DOH proposes using the 75% UCL and an SSM = 104 enterococcus from shore to the 1000-ft seaward limit. Our intent is to be more protective at heavily used beaches.

b. For Tier 2- Other Beaches, DOH proposes using the 82% UCL and an SSM = 158 enterococcus within the 1000-ft seaward limit.

Beyond 300 meters/1000 feet of shore:

c. Seaward of the 1000-ft boundary from shore out to the three-mile limit of State waters, DOH proposes using a standardized 95% UCL with an SSM = 501. (see Figure 1)

**Organization Name:** State of Hawaii Department of Health/Environmental Health Administration

**Document ID:** 195

**Comment ID:** 463

### **Comment:**

#### **The State's Preferred Options**

Given the options available in EPA's proposed rule, we recommend that only two tiers of beaches along with only two SSMs be incorporated into the final federal rule for Hawaii. (We believe that other states' preferences for their waters should be accommodated.) Two tiers will simplify the distinctions between the four proposed tiers and concentrate on protecting beaches that receive the highest use. The two tiers of beaches would both be within the State's present 300 meter/1000 foot marine recreational waters boundary (HAR sec. 11-54-08(b)).

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 346

### **Comment:**

The focus of the rule should be on designated beaches.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 350

### **Comment:**

The definitions for use levels are still too vague to ensure consistent application.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 371

**Comment:**

**Category Definitions:**

The rationale for the definitions on use level is peculiar, and the definitions themselves can still be applied in very different ways. For example, are states to base the intervals on the one designated beach in their state that has the highest visitor rates, or on an average of all designated beaches regardless of size or popularity. It also seems inappropriate for EPA to suggest that states are restricted to the degree to which they assign beaches of lesser visitor numbers to categories that would receive a higher degree of protection (more sensitive single sample maximums). This is particularly true since the single sample maximum limits are not based on health effects but on moderating the risk of saying a seldom-sampled beach is out of compliance when in fact it is in compliance. There is no clear rational basis to establish four levels of single sample maximums and EPA should just recommend a range of acceptable-probabilities for use when less than ten samples are used for calculating the geometric mean.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 373

**Comment:**

EPA suggests that states evaluate which use level category all of its marine waters are in for the purpose of applying the single sample maximum criteria; and suggests that the proposed definitions can be objectively applied when CWA actions are taken even though it is not included in the draft EPA rule. This seem unrealistic.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 374

**Comment:**

In addition to the problems noted previously in consistently interpreting the definitions on the use levels, we also have the problem that water bodies have multiple levels of use that occur along their shorelines and no assessment data exists to document and compare these. If the state does not have the data, then neither will EPA in its oversight role of NPDES permits.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 376

**Comment:**

We find that this alternative proposal is more workable then the one noted in III.B.2.a.; however, the same basic problems exist regarding uncertainty noted previously on applying the criteria (establishing point of compliance, averaging periods, relationship to geometric mean, etc.). We also still find no basis for the selection of the single sample maximum, but believe that if EPA is not going to ensure the use of the geometric mean as the mainstay of the bacteria criteria program then allowing the higher confidence levels (>75 percent) is not very defensible.



**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 377

**Comment:**

The fact that the 1986 criteria document established four possible risk levels for violating the geometric mean does not make that approach acceptable or technically defensible. Citing a prior unsupported policy decision is hardly a form of evidence on why that policy should be placed in a regulation. One size can certainly fit all in this case and the risk of ignoring a non-compliant beach can certainly be standardized.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 378

**Comment:**

**III. B.2.b. Paragraph 3:** Unless the single sample maximum is coupled with language that will require collection and analysis to determine if the geometric mean is being met, then it should not be included in the rule. It is relatively clear that it will not be used consistently between states, and it is our opinion that a federal rule that would override our state standards must ensure that it would be applied consistently and equitably between all affected states. If EPA has reason to believe that the single sample maximums are only applicable to designated beaches because these types of beaches are the ones that EPA studied, then it seems appropriate to apply the entire federal rule to only designated bathing beaches. EPA appears to be suggesting that it is the bather-to-bather transmission of disease that may have accounted for the illness rates. If EPA has retained the original study data, they may be able to verify this assumption by comparing bather density to disease rates.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 388

**Comment:**

EPA appears to be encouraging states to move away from the CWA goal of making all waters fishable and swimmable just to avoid coverage under the Beaches Act regulation. Is this really the message EPA is trying to send? If EPA believes that broad application of its criteria recommendation may result in more waters being removed from protection, then doesn't it seem reasonable to consider a more limited federal rule? Perhaps restricting the rule to designated beaches will be sufficient to mitigate the potential for states to broadly remove water contact recreation uses.

**Organization Name:** Surfrider Foundation

**Document ID:** 194

**Comment ID:** 118

**Comment:**

**Use of the Single Sample Maximum (SSM)**

First, regarding the various SSMs, Surfrider Foundation recommends use of only the upper 75% confidence level (e.g., 104/100 ml for enterococci) value. This is the most conservative and therefore, the most protective of human health.

**Organization Name:** Surfrider Foundation

**Document ID:** 194

**Comment ID:** 122

**Comment:**

**Categories of Coastal Recreation Waters**

Surfrider Foundation favors the approach of promulgating only the 75% confidence level SSM that would apply to all coastal recreation waters included in the final rulemaking. We can see no justification for applying one standard to a heavily-used beach and a lesser standard (higher SSM) to a lesser-used beach. All swimmers and surfers should be afforded the same protection, regardless of how many other people use a particular beach.

**Organization Name:** The City of New York Department of Health and Mental Hygiene

**Document ID:** 239

**Comment ID:** 142

**Comment:**

**Categorization of Coastal Waters:**

EPA has proposed the following definitions for each category of water body designated in Table 1:

*(1) Designated Bathing Beach Waters (upper 75% CL, marine SSM=104 per 100 ml):* Those coastal recreation waters that, during the recreation season, are heavily-used and may have: a lifeguard, bathhouse facilities, or public parking for beach access.

*(2) Moderate Use Coastal Recreation Waters (upper 82% CL, marine SSM=158 per 100 ml):* Those coastal waters that are not designated bathing water but typically, during the recreation season, are used by at least half of the number of people at typical designed bathing beach waters within the State.

*(3) Light Use Coastal Waters (upper 90% CL, marine SSM=276 per 100 ml):* Those coastal waters that are not designated as bathing beach but typically, during the recreational season, are used by less than half of the number of people typical at designated bathing beach waters within the state, but are more than infrequently used. States may also include infrequent use of coastal recreation waters in this category.

*(4) Infrequently Used Coastal Recreational Waters (upper 95% CL, marine SSM=501 per 100 ml):* Those coastal recreation waters that are rarely or occasionally used. Example of infrequent-use coastal recreation waters might include waters that are at remote locations, difficult to access, or infrequently used for primary contact recreation due to commerce or navigation.

**Comments:** We believe that it is difficult to adequately define such usage categories in a consistent manner both locally and nationally because bather intensity can fluctuate significantly from beach to beach, state to state, and day to day. Therefore, it is recommended that the categories of recreational waters be simplified from four to two: "Designated Bathing Beach Waters" and "Other Recreational (Primary Contact) Waters." The SSM of 104 per 100 ml (75% CL) or the locally derived equivalent using EPA methodology and the GM value should apply to

"Designated Bathing Waters." Only the GM value should apply to the "Other Recreational Waters" category.

**Organization Name:** The City of New York Department of Health and Mental Hygiene

**Document ID:** 239

**Comment ID:** 146

**Comment:**

The categorization of coastal recreation waters should be reduced from four to two: Designated Bathing Beach Waters and Other Recreation (Primary Contact) Waters. The enterococci GM (35 per 100 ml marine) applies to both categories and the 75% CL SSM (104 per 100 ml marine or locally derived equivalent) as explicitly defined above applies to Designated Bathing Waters only.

**Organization Name:** Wisconsin Department of Natural Resources

**Document ID:** 176

**Comment ID:** 110

**Comment:**

The Section agrees with the alternative option for categorization of coastal recreation waters in Section III. B. 2. b. titled, *Alternative Options for Categorization of Coastal Recreation Waters*. More specifically, the Department agrees that EPA should include only two (2) SSMs for coastal recreation waters: the 75% confidence level for all designated bathing beaches and a single other confidence level corresponding to the 95% confidence level for all other recreation waters. While Wisconsin is aware of the location of coastal beach areas, we do not have data available to categorize other recreation waters into the four categories. If this approach is used, the Department agrees that the interpretations of categories used for the SSMs be determined by the individual States. States and Territories differ in climate and high bather load at the beaches in Wisconsin will differ from high bather load at beaches in another State (example: Florida). The Section disagrees however, that the 75% confidence level for bathing beaches be applied to all recreational waters. This approach may have adverse impacts on water quality in the form of chlorine by-products, due to increased requirements for disinfection in waters that are infrequently used for full contact recreation.

**Response:**

See the preamble to today's rule, in particular, section IV.B., Criteria for Pathogen Indicators.

In addition, EPA would like to emphasize that the Agency is not designating uses as part of this rulemaking. The criteria in the final rule apply to those coastal marine and Great Lakes waters that specific States and Territories have designated for swimming, bathing, surfing, or similar water contact activities. This rule does not affect the ability of a State or Territory to conduct use attainability analyses.

Several commenters described approaches to implementing single sample maximums or the process by which they tier their coastal recreation waters. EPA appreciates this information.

EPA would like to remind commenters that States and Territories may calculate site-specific single sample maximums to account for variability at particular water bodies.

In deriving the definitions for use intensity categories, EPA consulted several readily available sources of information. These sources are by no means the definitive authorities on defining

intensity, but were offered up as easy to understand examples. See the proposed rule at 69 FR 41725 for more information. EPA notes that as described in Section IV. B. of the preamble, States and Territories have flexibility in assigning use categories to coastal recreation waters. States and Territories can use additional factors such as density of bathers to assist them in assigning coastal recreation waters to the different use categories.

## **Issue: Rules of Applicability for Federal Criteria**

**Organization Name:** Buckeye Florida

**Document ID:** 172

**Comment ID:** 243

**Comment:**

*Role of State/Territorial General Rules of Applicability* - Buckeye supports continued application of State/Territorial General Rules as EPA proposes.

**Organization Name:** Kansas Department of Health and Environment, Division of Environment, Bureau of Water

**Document ID:** 173

**Comment ID:** 199

**Comment:**

*Role of State/Territorial Rules of Applicability* - EPA requests comment on whether state's rules on such things as mixing zones, and dilution equations should be applicable in conjunction with the proposed criteria. Any state rule that is independent of the promulgated federal numeric bacteria criteria should, unquestionably, be independently applicable of EPA's promulgated numeric criteria.

**Organization Name:** NRDC, Clean Water Project

**Document ID:** 192

**Comment ID:** 207

**Comment:**

**Mixing Zones**

The US EPA's proposed rule nowhere mentions the use of "mixing zones" to permit compliance with pathogen criteria. NRDC opposes the use of mixing zones to comply with pathogen criteria for recreational waters, and asks EPA to insert into its proposed rule a requirement that mixing zones not be used. Use of mixing zones would not be as protective as the requirements in the 1986 water quality criteria document.

In the alternative, NRDC comments that, if mixing zones are allowed by the rule, EPA should add a requirement that they be used only in conjunction with permanent signage warning recreational users to not swim in the waters to which they apply since localized exceedances of EPA criteria will be authorized in those waters. In other words, if EPA is authorizing discharges that will violate its own public health-based standards, it should at least be doing so openly with appropriate and effective notice to the public of the increased risks.

**Organization Name:** New Jersey Department of Environmental Protection

**Document ID:** 178

**Comment ID:** 22

**Comment:**

*Role of State/Territory General Rules of Applicability* - The Department agrees with the rule as proposed which allows States to use mixing zones where State regulations authorize the use of such.

**Organization Name:** Wisconsin Department of Natural Resources

**Document ID:** 176

**Comment ID:** 115

**Comment:**

The Section further agrees that the Federal criteria for bacteria should be subject to States' general rules of applicability in the same way and to the same extent as other Federally adopted or State-adopted numeric criteria for coastal recreation waters (i.e. mixing zones).

**Response:**

See the preamble to today's rule, in particular section IV.C.2, Role of State/Territorial General Rules of Applicability.

EPA appreciates the general support expressed by the commenters for EPA's proposed approach towards general rules of applicability.

EPA appreciates the concerns of commenters regarding health risk of exposure to fecal contamination within mixing zones. However, EPA has determined that the Agency's existing guidance provides sufficient direction to permitting authorities as they implement State or Territorial mixing zone policies. EPA's Water Quality Standards Handbook: Second Edition (EPA-823-B-94) as well as EPA's Technical Support Document for Water Quality Based Toxics Control (EPA-505-2-90-001) advise against the use of mixing zones where the location may pose a significant health risk. These documents stress the importance of determining the appropriate placement and size of mixing zones depending on the potential effects to human health and the environment. As a result, EPA declines to prohibit the application of mixing zones in the final rule.

EPA decided not to add a requirement that mixing zones be used only with permanent signage warning users not to swim in those waters because such a requirement is beyond the scope of a water quality standards rule.

**Issue: SSM****Organization Name:** American Forest and Paper Association**Document ID:** 191**Comment ID:** 483**Comment:**

Lastly, AF&PA holds that the rule should clarify that multiple samples should be used to effectively determine the impairment status of recreational waters, as opposed to the single sample maximum values called for in the proposed rule.

**Organization Name:** Association of Metropolitan Sewerage Agencies**Document ID:** 227**Comment ID:** 285**Comment:**

*Interpretation of "Single Sample Maximum"*

In the July 9 proposal's preamble, EPA seeks comment on interpretations of the term "single sample maximum (SSM)" because the 1986 criteria document does not interpret the meaning of the term. EPA posits that one possible interpretation is that the SSM is a single value never to be exceeded. AMSA strongly disagrees with this interpretation, as it is inconsistent with other EPA guidance and not reflective of the level of protection the 1986 criteria are intended to provide.

**Organization Name:** Association of Metropolitan Sewerage Agencies**Document ID:** 227**Comment ID:** 287**Comment:**

*AMSA's Recommended Approach*

The BEACH Act requires EPA to promulgate criteria that are "as protective of human health as" the 1986 criteria. The interpretation of the SSM is critical to demonstrating whether the criteria are in fact "as protective." As stated above, the 1986 criteria document does not interpret the term "single sample maximum," discusses SSMs solely in the context of beach closures, and states that "in deciding whether a beach should be left open, *it is the long term geometric mean bacterial density that is of interest. Because of day-to-day fluctuations around this mean, a decision based on a single sample (or even several samples) may be erroneous, i.e., the [single] sample may exceed the recommended mean criteria even though the long-term geometric mean is protective, or may fall below the maximum even if this mean is in the nonprotective range*" (January 1986; page 9).

The May 2002 draft bacteria implementation guidance (page 5) further indicates that "[i]n terms of criteria setting, the targeted level of protection is the illness rate, *and the most direct relationship between measurements of bacterial levels and illness rate is the geometric mean of measurements taken over the course of a recreation season.*" This is consistent with the proposal's preamble statement at 41725 that "the geometric mean has the most direct relationship to the illness rate." Therefore, as EPA goes on to say in the preamble, "EPA could interpret the phrase 'as protective of health as' the 1986 bacteria criteria document *to apply only to the geometric mean.*" AMSA believes this is the most reasonable interpretation and recommends that

EPA only promulgate the geometric mean in the final rule, leaving the SSM available for use as an implementation tool for making beach opening and closure decisions only.

### *C. Alternative Limited Application Approaches*

EPA's May 2002 draft bacteria implementation guidance (page 46) recommends that states use only the geometric mean component for National Pollutant Discharge Elimination System (NPDES) water quality-based effluent limits. AMSA strongly recommends that the regulatory text, if EPA insists that it include the SSM in the criteria, be modified to plainly state that the SSM is to be used only for making beach closure and opening decisions as originally intended in the 1986 criteria document, and not for assessing attainment of standards, developing total maximum daily loads (TMDL)s or developing NPDES permit limits.

Alternatively, if EPA will not clearly limit use of the SSM to beach opening/closing decisions, AMSA recommends that EPA modify the proposed regulatory text to state that the SSM shall not be exceeded only when there is insufficient data to determine that the geometric mean criterion is being met. A sufficient number of samples for comparison with the geometric mean criterion provide an indication of swimming-associated health risks superior to reliance on single values from single samples. Where a statistically sufficient number of samples is available (at least five tests evenly spaced over thirty days, according to EPA), application of the geometric mean criterion is as protective as application of a SSM criterion set equal to a confidence limit where such a data set does not exist. The SSM is a surrogate for the geometric mean in the absence of a suitably large data set to protect against the risk of exceeding the geometric mean. Therefore, in the presence of a suitably large data set, reliance upon the geometric mean criteria from the 1986 bacteria criteria document completely satisfies the "as protective as" test.

**Organization Name:** Buckeye Florida

**Document ID:** 172

**Comment ID:** 235

**Comment:**

Single Sample Maximum (SSM) interpretation - The EPA epidemiological studies showed a correlation between the geometric mean and gastroenteritis. No studies were presented showing connection to SSMs. Therefore, Buckeye supports the establishment of the water quality criteria based on the geometric mean only. SSMs should continue to be used as guidance for use only in public health decisions like beach closures. Obviously, if a SSM is exceeded often, the geometric mean will be exceeded.

**Organization Name:** Buckeye Florida

**Document ID:** 172

**Comment ID:** 238

**Comment:**

*Alternative Options for Categorization of Coastal Recreation Waters* - Again, the use of the geometric mean as the water quality criteria and using the SSMs for public health decisions at beaches precludes the need to issue this guidance. EPA acknowledges the benefits of a simplified approach by limiting the number of SSMs, yet also acknowledges that "one size does not fit all". The use of the geometric mean only water quality criteria provides the beneficial simplification desired while still expecting states and territories to adopt their own criteria that can include SSMs if appropriate and defensible.



**Organization Name:** California Regional Water Quality Control Board

**Document ID:** 203

**Comment ID:** 94

**Comment:**

**Use of the Single Sample Maximum**

"The 1986 bacteria criteria document does not interpret the meaning of the term "single sample maximum". One interpretation is that it [the SSM] is a single value never to be exceeded."

The Regional Board agrees that this is a valid definition that should be used for both beach closure and opening decisions and for water quality assessments and regulation of discharges. The main opposition to the inclusion of SSMs in water quality standards appears to be the high day-to-day variability in bacteria density in single samples. Nonetheless, a direct correlation exists between the density of bacteria in a single sample and the likelihood of contracting a swimming-associated illness. The Santa Monica Bay Restoration Project epidemiological study found that swimming in waters contaminated by urban runoff increases the risk for coughing with phlegm, vomiting, ear discharge, chills, and significant respiratory diseases (fever and nasal congestion, fever and sore throat, etc.). The study analyzed the relationship between the total-to-fecal coliform ratio, previously studied bacterial indicators (total coliform, fecal coliform, *E. coli*, and enterococcus), and adverse health effects from urban runoff into ocean waters. The study found "a direct, linear relationship between swimming-associated gastrointestinal illness and the quality of the bathing water," showing a correlation between SSM values and illnesses.<sup>1</sup> In short, the greater the density of indicator bacteria in a single sample, the greater the likelihood of swimming-associated illnesses.

**Footnote:**

<sup>1</sup>*Santa Monica Bay Beaches Wet-Weather Bacteria TMDL*. Nov. 7, 2002. California Regional Water Quality Control Board, Los Angeles Region. See also Haile, R.W., et al. 1996. "An epidemiological study of possible adverse health effects of swimming in Santa Monica Bay". Prepared for the Santa Monica Bay Restoration Project; and Haile, R.W., et al. 1999. "The health effects of swimming in ocean water contaminated by storm drain runoff." *Epidemiology* 10(4):355-363

**Organization Name:** California Regional Water Quality Control Board

**Document ID:** 203

**Comment ID:** 96

**Comment:**

"EPA could ...interpret the 1986 bacteria criteria document as recommending the use of SSMs only for decisions related to public health at beaches. Under this interpretation, SSMs would be part of the water quality criteria, but only used for making beach closure and opening decisions. The SSMs would be available for use as an implementation tool for making beach opening and closure decisions but would not be part of the applicable water quality standards."

The Regional Board disagrees with these statements. The SSMs should be part of the water quality standards for both beach closure and opening decisions and for water quality assessments and regulation of discharges. They should not be merely implementation tools for making beach closure and opening decisions given the direct relationship that exists between the density of bacteria in a single sample and the likelihood of contracting a swimming-related illness.

Additionally, removing SSMs from water quality standards will create an inconsistent and confusing situation in California with respect to beach postings by the local health departments versus water quality assessments for water contact recreation beneficial uses by the Regional Board. Based on the results of the Santa Monica Bay epidemiological study, the State legislature incorporated minimum bacteriological standards into the California Code of Regulations (CCR), including standards for total coliform, fecal coliform, and enterococcus. These water quality standards are used for making beach closure and posting decisions by local public health agencies (CCR Title 17, Article 4, section 7985, Bacteriological Standards). If the U.S. Environmental Protection Agency (USEPA) promulgates bacteria criteria for California (excluding the Los Angeles Region) without including a SSM criterion, the following scenario is likely to arise. The local health departments would post beaches with public health warnings when the SSM standards contained in State law are violated. However, if the geometric mean criteria were not exceeded, the Regional Boards would consider the water contact recreation designated use to be fully supported by the existing water quality. So, in spite of the fact that beaches would be posted with health risk warnings, the water quality would not be considered impaired for water contact recreation, and the Regional Board would have no compelling basis to regulate discharges to improve water quality.

**Organization Name:** California Regional Water Quality Control Board

**Document ID:** 203

**Comment ID:** 98

**Comment:**

"...EPA could interpret the phrase "as protective of human health as" the 1986 criteria document to apply only to the geometric mean. Under this interpretation, EPA would promulgate only the geometric mean in the final rule."

The Regional Board disagrees with this approach given the findings of the Santa Monica Bay epidemiological study, which showed a direct link between single sample bacteria densities and increased risk of swimming-related illness. We believe that USEPA must interpret "as protective of human health as" the 1986 bacteria criteria document to include both SSM and geometric mean criteria.

**Organization Name:** California Regional Water Quality Control Board

**Document ID:** 203

**Comment ID:** 104

**Comment:**

From a public health perspective,<sup>4</sup> adopting conservative water quality standards that include SSMs is the responsible approach until there is definitive evidence that water quality meeting geometric mean objectives alone will fully support contact recreation beneficial uses. The interests of the people of our nation are best served by limiting the possibility of illness due to water contact recreation. The two-tiered approach of SSM and geometric mean objectives should be retained by the USEPA in its final rulemaking.

While the Los Angeles Regional Board supports the use of both SSM and geometric mean limits in setting bacteria water quality standards, the California State Water Resources Control Board (State Board) is proposing to amend the bacterial water-contact standards in the California Ocean Plan to remove SSM objectives and use SSM limits as merely triggers for additional monitoring. The State Board will consider the proposed amendment to the California Ocean Plan in October 2004 and, if adopted, will seek US EPA approval of the plan. The Los Angeles Regional Board is

opposed to this change to the California Ocean Plan because, for the reasons discussed in this letter, it is not as protective as the USEPA recommended 1986 criteria and is inconsistent with related State law.

**Footnote:**

<sup>4</sup> "In 2002, a study by the Centers for Disease Control and Prevention concluded that the incidence of infections associated with recreational water use has steadily increased over the last several decades. The increase is attributed to both better reporting and an actual increase in the number of people becoming ill." Natural Resources Defense Council. *Testing the Waters 2003: A Guide to Water Quality at Vacation Beaches*.

**Organization Name:** California Regional Water Quality Control Board, San Diego Region

**Document ID:** 199

**Comment ID:** 108

**Comment:**

**Use of Single Sample Maximum**

"One interpretation is that [SSM] is a single value never to be exceeded."

The Regional Board agrees that this is a valid definition that should be used for both beach closure and opening decisions and for water quality assessments and regulation of discharges. The main opposition to the inclusion of SSMs in water quality standards appears to be the high day-to-day variability in bacteria density in single samples. Nonetheless, a direct correlation exists between the density of bacteria in a single sample and the likelihood of contracting a swimming-associated illness. The Santa Monica Bay Restoration Project epidemiological study found that swimming in waters contaminated by urban runoff increases the risk for coughing with phlegm, vomiting, ear discharge, chills, and significant respiratory diseases (fever and nasal congestion, fever and sore throat, etc). The study analyzed the relationship between the total-to-fecal coliform ratio, previously studied bacterial indicators (total coliform, fecal coliform, *E. coli*, and enterococcus), and adverse health effects from urban runoff into ocean waters. The study found "a direct, linear relationship between swimming-associated gastrointestinal illness and the quality of the bathing water," showing a correlation between SSM values and illnesses.<sup>1</sup> In short, the greater the density of indicator bacteria in a single sample, the greater the likelihood of swimming-associated illnesses.

**Footnote:**

<sup>1</sup> *Santa Monica Bay Beaches Wet-Weather Bacteria TMDL*. Nov 7, 2002, California Regional Water Quality Control Board, Los Angeles Region.

**Organization Name:** California Regional Water Quality Control Board, San Diego Region

**Document ID:** 199

**Comment ID:** 111

**Comment:**

"SSMs would be part of the water quality standard, but only for making beach closure and opening decisions."..."The SSMs would be available for use as an implementation tool for making beach opening and closure decisions but would not be part of the applicable water quality standards."

The Regional Board disagrees with these statements. The SSMs should be part of the water quality standards for both beach closure and opening decisions and for water quality assessments and regulation of discharges, not merely implementation tools for making beach closure and opening decisions, because a direct relationship exists between the density of bacteria in a single sample and the likelihood of contracting a swimming-related illness.

Additionally, excluding SSMs from the standards for water quality assessments will create an inconsistent and confusing situation in California with respect to beach closings by the local health departments versus water quality assessments for contact recreation beneficial uses by the Regional Board. The California Code of Regulations (CCR) contains SSMs for all three bacterial indicators as part of the water quality standards for making beach closure and opening decisions by local public health agencies (CCR Title 17, Article 4, section 7985, Bacteriological Standards). If the U.S. Environmental Protection Agency (USEPA) promulgates the criteria without SSMs as part of water quality standards for assessments, during wet weather conditions, the following scenario is likely to arise. The local health departments would close beaches when the SSM standards are violated. However, if the geometric mean criteria are not exceeded, the Regional Board would consider contact recreation beneficial uses to be fully supported by the existing water quality. So, in spite of the fact that beaches would be closed and posted with health risk warnings, the water quality would not be considered impaired for contact recreation, and the Regional Board would have no compelling basis to regulate discharges to improve water quality.

**Organization Name:** California Regional Water Quality Control Board, San Diego Region

**Document ID:** 199

**Comment ID:** 112

**Comment:**

"...EPA could interpret the phrase 'as protective of human health as' the 1986 criteria document to apply only to the geometric mean."

The Regional Board disagrees. We believe that USEPA must interpret "'as protective of human health as' the 1986 bacteria criteria document" to include both SSMs and geometric means for all water quality criteria.

**Organization Name:** California Regional Water Quality Control Board, San Diego Region

**Document ID:** 199

**Comment ID:** 114

**Comment:**

"...EPA would promulgate only the geometric mean in the final rule."

The Regional Board disagrees. Based on the above discussion, SSMs should be promulgated in the final rule along with geometric means.

**Organization Name:** California Regional Water Quality Control Board, San Diego Region

**Document ID:** 199

**Comment ID:** 124

**Comment:**

From a public health perspective,<sup>4</sup> adopting conservative water quality standards that include SSMs is the responsible approach until there is definitive evidence that water quality meeting geometric mean objectives alone will fully support contact recreation beneficial uses. The

interests of the people of our nation are best served by limiting the possibility of illness due to water contact recreation. The two-tiered approach of SSM and geometric mean objectives should be retained by the USEPA in its final rule-making.

This approach is in opposition to a proposal by the California State Water Resources Control Board (State Board) to amend the bacterial water-contact standards in the California Ocean Plan. The State Board's proposed amendment re-defines the single sample maximum standard values to be triggers for additional monitoring rather than part of regulatory standards. The State Board will consider the proposed amendment to the California Ocean Plan in October 2004, and if adopted will seek USEPA approval of the plan. The Regional Board is opposed to this change to the California Ocean Plan because, for the reasons discussed in this letter, it is not as protective as the USEPA 1986 criteria.

**Footnote:**

<sup>4</sup> "In 2002, a study by the Centers for Disease Control and Prevention concluded that the incidence of infections associated with recreational water use has steadily increased over the last several decades. The increase is attributed to both better reporting and an actual increase in the number of people becoming ill." Natural Resources Defense Council. *Testing the Waters 2003: A Guide to Water Quality at Vacation Beaches*.

**Organization Name:** California Stormwater Quality Association

**Document ID:** 202

**Comment ID:** 129

**Comment:**

**Issue:** Definition or explicit interpretation of the term "single sample maximum"

The 1986 bacteria criteria document does not interpret the meaning of the term "single sample maximum." USEPA is seeking public comment on whether to include an explicit interpretation or definition of this term in the final regulatory text. Possible interpretation options include:

- a. The single value is never to be exceeded;
- b. Allow for exceedance of the SSM when making attainment decisions because bacterial measurements are inherently variable, due to a number of factors that may not necessarily reflect underlying water quality. An unacceptably high value for any given individual sample may be used to trigger a beach advisory or closing or additional monitoring or it may be evaluated with other sample results, but would not necessarily be used alone to determine nonattainment of the water quality standards;
- c. SSMs would be part of the water quality criteria, but only used for making beach closure and opening decisions. States could use only the geometric mean for other CWA purposes (NPDES permitting, TMDLs, etc.).

If the SSM is to be included in the final criteria then CASQA supports an explicit interpretation of the term "single sample maximum." Based on our experience we support the interpretation noted in item b above. Our experience in California, especially with southern California beaches, is that the use of a single value for making attainment decisions is inadequate at best and erroneous at worst. The sporadic, episodic, and variable nature of bacteria violations in the surf zone makes the use of single values for attainment issues unreasonable.

**Organization Name:** California Stormwater Quality Association

**Document ID:** 202

**Comment ID:** 131

**Comment:**

**Issue:** Use of Geometric Mean "as protective of human health"

USEPA is considering the interpretation of the phrase "as protective of human health as" in the 1986 bacteria criteria document to only apply to the geometric mean. Similarly the SSM would be available for use as an implementation tool for making beach opening and closure decisions but would not be part of the applicable water quality standards. States would have flexibility to use the SSMs in this or any other application of the water quality standards, as they deem appropriate. CASQA supports this interpretation for a couple of reasons. First as stated in the proposed rule, USEPA in its epidemiological studies on coastal and Great Lakes waters used the geometric mean as the value to correlate with average gastrointestinal illness rate. Thus the use of a geometric mean has a more direct correlation with the intended purpose of the proposed rule. Second, the SSMs should be used more for identifying problematic water bodies and not for compliance assessment. Rather the SSMs should be used in the water quality standard implementation process. Should USEPA decide to include SSMs in the final criteria then CASQA supports the opportunity for each State to develop their own site specific SSMs. Current monitoring efforts in California provide a significant database for the development of SSMs that reflect local conditions and uses.

**Organization Name:** County of Orange, CA/RDMD/Watershed and Coastal Resources Division

**Document ID:** 193

**Comment ID:** 178

**Comment:**

The term "single sample maximum" should be interpreted as meaning: allowance of exceedence of the SSM when making attainment decisions because bacterial measurements are inherently variable, due to a number of factors that may not necessarily reflect underlying water quality. An unacceptably high value for any given individual sample may be used to trigger a beach advisory or closing or additional monitoring or it may be evaluated with other sample results, but should not be used alone to determine nonattainment of the water quality standards.

**Organization Name:** County of Orange, CA/RDMD/Watershed and Coastal Resources Division

**Document ID:** 193

**Comment ID:** 179

**Comment:**

The interpretation of the phrase "as protective of human health as" from the 1986 bacteria criteria document should be applicable only to the geometric mean. Under this interpretation EPA would promulgate only the geometric mean in the final rule, and the SSMs would be available for use as an implementation tool for making beach opening and closure decisions but would not be part of the applicable water quality standards.

**Organization Name:** Department of Environmental Services City and County of Honolulu

**Document ID:** 235

**Comment ID:** 298

**Comment:**

Section 131.41(c)(2)

We feel that single sample maximum (SSM) values should not be part of the WQS because the values were not determined from data taken from Hawaiian waters. The SSM values perhaps could be used to serve as triggers for beach closures or additional sampling. In this case, defining "coastal recreation water" categories would not be necessary.

**Organization Name:** Florida Department of Environmental Protection

**Document ID:** 229

**Comment ID:** 76

**Comment:**

We agree that the phrase "as protective of human health as" the 1986 criteria document applies only to the geometric mean. The department's data indicate that the majority of determinations of impairment are attributable to exceedences of the geometric means, while natural variability is highly likely to cause exceedences of the Single Day Maxima. We encourage EPA to promulgate only the geometric mean in the final rule. The Single Sample Maxima are available as implementation tools for making beach opening and closure decisions but should not be part of the applicable water quality standards. The department is compiling our data in support of this recommendation and will submit the information in the next couple of weeks.

**Organization Name:** Florida Department of Environmental Protection

**Document ID:** 229

**Comment ID:** 77

**Comment:**

In Florida we have used the term "single sample maximum" to imply a level not to be exceeded. However, the enterococci and *E. coli* single sample maxima in the 1986 criteria document are percentiles of the range of data that went into deriving the geometric mean. Therefore, it is reasonable to expect that these single sample maxima will be exceeded proportionate to their percentile rank. We believe the best use of the single sample maxima limits in the 1986 criteria document will be as recreation advisory levels not as water quality criteria.

**Organization Name:** Hampton Roads Sanitation District

**Document ID:** 220

**Comment ID:** 228

**Comment:**

While the proposed rule does not apply to Virginia because it has already adopted the 1986 proposed criteria including the use of single sample maximum concentrations (SSM), the application of the SSM is causing an increase in the number of beach closings and potential listing of waters as impaired under 303(d).

HRSD believes strongly that any of the options that rely on SSM concentrations for regulatory decisions are inappropriate due to normal variability of results due to bacterial analytical methods and sampling.

**Organization Name:** Hampton Roads Sanitation District

**Document ID:** 220

**Comment ID:** 233

**Comment:**

EPA should promulgate only the geometric mean of bacterial density in the final rule. SSMs would be available for use as an implementation tool for making beach opening and closure decisions, but would not be part of the applicable water quality standards.

**Organization Name:** Jeffrey A. MacDonald

**Document ID:** 177

**Comment ID:** 50

**Comment:**

**Issue** - Use of a Geometric Mean (GM) or a Single Sample Maximum (SSM) when applying an *E. coli* standard to a WPDES holder.

A portion of the proposed rule reads, "...the geometric mean has the most direct relationship to the illness rate. With this in mind, EPA could interpret the phrase "as protective of human health as" the 1986 bacteria criteria document to apply only to the geometric mean...The SSMs would be available for use as an implementation tool for making beach opening and closure decisions but would not be part of the applicable water quality standards."

Since the GM is more directly tied to illness rate than is a SSM, it would be appropriate to use only the GM for regulation of NPDES holders. The SSM should only be used in beach opening and closing decisions. I strongly recommend regulation solely by a geometric mean, with no single sample maximum in the regulation for NPDES permit holders. It is beneficial to have a large data set when developing a geometric mean for NPDES permit monitoring. Sampling three times per week for small-to-moderate dischargers, and daily for large dischargers (>10 million gallons per day), would be reasonable frequencies for calculating monthly GMs.

**Organization Name:** Kansas Department of Health and Environment, Division of Environment, Bureau of Water

**Document ID:** 173

**Comment ID:** 197

**Comment:**

*Use of Single Sample Maximum* - EPA requested input on alternatives for using single sample maximum (SSM) criteria. KDHE would suggest a hybrid approach incorporating elements of two of the proposed alternatives. The hybrid would provide for SSMs that could be used for beach closures, **and** allow to states to choose whether to use the SSMs for use attainability decisions for 305b and 303d purposes. The current proposals state that 1) *only* a geometric mean could be used for Clean Water Act purposes; or 2) SSMs would be "*available as an implementation tool.*" The first alternative eliminates state's ability to use SSMs for attainability and permitting decisions. The second implies the SSM would not be regulatory in nature, thus making it questionable if it would be enforceable in determining impairment.

The hybrid would allow the SSMs to be regulatory in nature for beach closures, while leaving up to state to determine whether to use SSMs for attainability decisions. The hybrid would also provide maximum flexibility for state implementation.

**Organization Name:** King County Department of Natural Resources and Parks

**Document ID:** 158

**Comment ID:** 267



**Comment:**

We at King County in Washington State have significant concerns about this action and want to comment on the options EPA are considering. In each part of the rule EPA is asking for comment on has significant issues, not the least of which is the application of a single sample maximum along with a geomean. For any utility or municipality in the midst of long term control plan for CSOs, it can be assured that for a few hours periodically, there will be opportunities to exceed the standards being proposed. Such exceedances would lead to listing of waterbodies and TMDLs solely on the exceedance of that single daily maximum. This is not wise policy or appropriate use of EPA's override of state delegated' authority, particularly when the states will be the ones that will have to prepare the TMDLs such actions would necessitate.

**Organization Name:** Maryland Association of Municipal Wastewater Agencies

**Document ID:** 201

**Comment ID:** 27

**Comment:**

First, we are opposed to EPA mandating the adoption of the upper percentile values in the 1986 criteria document. We believe the geometric mean is the appropriate regulatory requirement. We have used geometric means solely here in Maryland for years. We are not opposed to EPA authorizing states to choose and use upper percentile values where data to calculate the geometric mean are not available or where the UPVs are used in an advisory (i.e., non-regulatory) capacity.

**Organization Name:** Maryland Association of Municipal Wastewater Agencies

**Document ID:** 201

**Comment ID:** 28

**Comment:**

Second, regardless of what standard EPA chooses to impose in the final rule, EPA should follow its November 2003 guidance and make clear that for attainment, TMDL, and NPDES permitting purposes, only the geometric mean should be applied (again, where there is at least four samples during each month). Again, we have used only a geometric mean for years in our discharge permits and have never had a problem.

**Organization Name:** Massachusetts Department of Environmental Protection

**Document ID:** 208

**Comment ID:** 60

**Comment:**

The single sample maximum (SSM) should be used for operational decisions involving beaches, but not in assessments of other ambient waters. Only the swimming season geometric mean should be used for assessing non-beach waters.

**Organization Name:** Massachusetts Water Resources Authority

**Document ID:** 245

**Comment ID:** 174

**Comment:**

The geometric mean is a better water quality attainment measure than a Single Sample Maximum (SSM) in coastal recreational waters. The SSMs are based on arbitrary percentiles of the distribution of the study population(s). MWRA is unaware of any epidemiological evidence

supporting these percentiles. Therefore, the least restrictive use and interpretation of these SSMs is appropriate. The geometric mean, as a measure of central tendency, is a more accurate indicator of water quality because bacteria concentrations can be highly variable in the environment. SSMs are short term measures of water quality, and provide appropriate guidance for rapid responses that serve public health - triggering beach advisories, closing, additional monitoring, or further evaluation, depending on the use category. If SSMs were included as a water quality attainment measure, CWA violations would likely increase, creating the public perception that water quality had degraded. This perception undermines treatment improvements that have already been implemented or planned at significant cost to meet existing standards. For water body assessments and TMDLs, the criterion should be limited to the geometric mean. It is imperative that EPA makes it clear to States that the SSM should be used as a recreational water quality guideline and NOT be used as a water quality attainment measure.

**Organization Name:** Massachusetts Water Resources Authority

**Document ID:** 245

**Comment ID:** 177

**Comment:**

The most troubling implication of this proposed rule is that if enterococcus and *E. coli* are adopted as water quality criteria for recreational waters, these standards will be incorporated into "DES discharge permits as is, without further consideration of applicability to wastewater treatment. This is of great concern because it has not been demonstrated that all treatment facilities will be able to comply these new standards, particularly the SSM. The SSM should only be used as a recreational water guideline and not as a water quality attainment measure. Maximum flexibility should be allowed in implementation of these proposed criteria, with emphasis placed on their effective use as recreational water guidelines and not as discharge limits for wastewater until the wastewater treatment of enterococcus is better understood.

**Organization Name:** Milwaukee Metropolitan Sewerage District

**Document ID:** 196

**Comment ID:** 185

**Comment:**

Regarding the promulgation of a "**single sample maximum**", we strongly urge against the interpretation of such as standard as a single value never to be exceeded. As noted in the preamble to the proposed rule, bacterial measurements are inherently variable, due to a number of factors not necessarily reflective of underlying water quality. Since the GM is more directly tied to illness rate than is a SSM, it would be appropriate to use only the GM for regulation of WPDES holders. The SSM should only be used in beach opening and closing decisions. We strongly recommend regulation solely by a geometric mean, with no single sample maximum in the regulation for WPDES permit holders. Therefore, we urge you to promulgate a final rule which contains only a geometric mean; making the SSMs available for use as an implementation tool possibly for making beach opening and closure decisions, but not a part of applicable water quality standards.

**Organization Name:** NRDC, Clean Water Project

**Document ID:** 192

**Comment ID:** 209

**Comment:****Integrating WQS into NPDES Permits**

The BEACH Act anticipated that relevant criteria would be integrated formally into the Clean Water Act's regulatory system. A plain reading of statutory text outlines that BEACH Act water quality standards merely amend those provided for in described in sections 302 and 303 of the Clean Water Act. 33 U.S.C. at 1312, 1313. EPA's guidance on this issue, as put forth in the *Draft Implementation Guidance for Ambient Water Quality Criteria for Bacteria*, requires that the permitting authority develop permits designed to attain water quality standards. *Draft Implementation Guidance for Ambient Water Quality Criteria for Bacteria*, at 5.2.1; see 40 C.F.R. 122.44 (d). While this statement is consistent with the Clean Water Act, the guidance suggests elsewhere that states have ultimate discretion as to how water quality standards will be attained. *Id.* at 5.2.2. Given uncertainty within the regulated community, this guidance does not provide adequate clarification that all NPDES permits authorizing discharges into waters covered by the BEACH Act must ensure compliance with the new bacterial standards, including through setting water-quality based effluent limits when necessary to achieve compliance. We ask EPA to inform clearly the regulated community, including publicly owned treatment works, of their obligation to meet these water quality standards.

**Organization Name:** National Council for Air and Stream Improvement, Inc.

**Document ID:** 189

**Comment ID:** 43

**Comment:**

Finally, NCASI is concerned about the potential use of single sample maximum (SSM) values for determining the status of waters relative to impairment listing under Clean Water Act section 303(d). As expressed in the proposed rule, the purpose of SSM values is as a guide for protecting the health of those using recreational waters. While the use of single water quality measurements is appropriate for the protection of human health, it is clearly inadequate for assessing the spatial and temporal quality of a water body. This is particularly true for bacterial indicator assays because the degree and extent of contamination can be very localized in time and space. The proposed rule should clarify that the geometric mean is the more appropriate value against which water impairment should be judged, and that multiple samples will be needed to adequately characterize the spatial and temporal variation needed to interpret the impairment status of water.

**Organization Name:** New Jersey Department of Environmental Protection

**Document ID:** 178

**Comment ID:** 18

**Comment:**

**The interpretation of "single sample maximum" as a single value never to be exceeded (p. 41725; 1st column).**

For waters having Geometric mean (Gm) values equivalent to the acceptable Gm, the single sample maximum (SSM) numbers are exceeded 25%, 18%, 10% or 5% of the time depending upon which SSM value is used (*i.e.*, the 75%, 82%, 90%, or 95% value). So, the above interpretation hardly seems appropriate. NJ never makes a beach closure decision based on a single exceedence of an SSM value. Such an exceedence is used as a trigger for additional monitoring.

**Organization Name:** New Jersey Department of Environmental Protection

**Document ID:** 178

**Comment ID:** 20

**Comment:**

**The use of single sample maximum (SSM) values only for beach closure and opening decisions.**

New Jersey supports this approach. There are only 2 occasions when SSM values are useful. One, when there is an "immediate" need to know whether or not the sanitary quality of a water body is acceptable. That is, a regulatory body does not have time to wait 30 days to collect 5 or more equally-spaced samples to determine whether or not it is safe to swim. The only situation where immediate decisions are required is at regulated (*i.e.*, lifeguarded) beaches. At regulated beaches, the regulating authority must establish each day, few days or each week whether or not the sanitary quality of the bathing water is acceptable. The second case is when there is not enough data from a given location (< 5 samples over 30 days) to calculate a Gm. For all other Clean Water Act purposes, SSM values are not needed. Thus, SSMs should be specified (but see below) for beach closure decisions, and perhaps listed as "guidance values only" for locations, which do not have sufficient data to calculate a valid Gm. **Only the Gm can and should be the basis of an applicable water quality standard.**

**Organization Name:** North Carolina Dept. of Environment and Natural Resources

**Document ID:** 190

**Comment ID:** 465

**Comment:**

*Single Sample Maximum (SSM)*

The State supports removal of the single sample maximum (SSM) from the EPA proposed water quality criteria. We believe strongly in the use of a single sample maximum when making rapid or short-term decisions related to public health at beaches and have placed the SSM in current NC public health regulations. We believe that the BEACH Act "as protective of human health as" applies *only to the geometric mean* as defined in the 1986 Ambient Water Quality Criteria for Bacteria document. The State of North Carolina additionally supports the use of a geomean to determine NPDES permitting, TMDLs and waterbody assessments that require management responses over an extended period of time.

We understand the single-sample maximum (SSM) statistical approach to estimate the geomean compliance, but believe that the use should be limited to management decisions for coastal recreation beach advisory programs *and not applied as a water quality standard*. We understand EPA is currently promulgating a water quality standard in NC to be compliant with the BEACH Act. However, we request acknowledgement that our "Coastal Recreational Waters Monitoring, Evaluation, and Notification" regulations (15A NCAC 18A .3400) adequately address the single sample maximum (SSM) issues and that there be no SSM within the promulgated standard.

**Organization Name:** North Carolina Dept. of Environment and Natural Resources

**Document ID:** 190

**Comment ID:** 481

**Comment:**

Nonetheless, we support the use of a central tendency statistic rather than a single sample maximum for bacterial water quality standards.

**Organization Name:** Northeast Ohio Regional Sewer District

**Document ID:** 198

**Comment ID:** 304

**Comment:**

Due to the magnitude of the implications for POTWs including the NEORSD, the NEORSD's comments focus on the interpretations of the term "single sample maximum" ("SSM") as they appear in Section III.B.1 of the proposed rule's preamble. Specifically, we cannot more strongly disagree with the first interpretation presented in the preamble and selected for the proposed rule interpreting that the SSM is to be applied as "a single value never to be exceeded." This interpretation creates an unreasonable standard for many waters because:

- Adoption of a never-to-exceed SSM is more protective than mandated;
- Adoption of a never-to-exceed SSM would discourage more extensive sampling and have the unintended effect of reducing the level of protection;
- Criteria Document statements do not necessitate never-to-exceed SSM adoption.
- The EPA cost analysis greatly underestimates the proposed rule's impact;
- The State of Ohio's existing *E. coli* criteria are at least as protective as the Federal criteria.

Furthermore, full attainment of the standard is impossible in the vicinity of upstream combined sewer overflows ("CSOs") or any significant urban or agricultural runoff. Elaboration on each of the above comments is presented below and in the attachments.

***Adoption of a never-to-exceed SSM is more protective than mandated.***

The Beaches Environmental Assessment and Coastal Health Act of 2000 ("BEACH Act") mandates that States adopt water quality criteria and standards "that are as protective of human health as the criteria for pathogens and pathogen indicators for coastal recreation waters published by the Administrator..." (Paragraph (i)(1)(A) of Section 2). The relevant consideration for determining consistency of State criteria with Federal criteria under the BEACH Act is therefore the level of risk to human health.

In *Ambient Water Quality Criteria for Bacteria* - 1986 ("Criteria Document"), EPA established an acceptable level of risk to human health for freshwater at a swimming associated gastrointestinal illness rate of 8 per 1,000 swimmers. The Criteria Document associated this illness rate with a geometric mean *E. coli* density of 126 per 100 mL. Also published in the Criteria Document were values termed "one-sided confidence limits" that, according to the document, "no sample should exceed." However, as explained below and demonstrated in Attachment A, when applied as a SSM never to be exceeded, these values are indicative of levels of risk to human health that are lower than the acceptable level of risk established in the Criteria Document.

For example, consider that the 75 percent "confidence limit" in the Criteria Document represents the value which 25 samples would be expected to exceed in a 100-sample data set with a geometric mean at the acceptable illness rate. To establish that this value is never to be exceeded is to deem as unacceptable those highest 25 samples collected at the acceptable illness rate. Excluding those 25 samples shifts the geometric mean downward to a value lower than the

geometric mean associated with the acceptable illness rate established in the Criteria Document. (Attachment A includes this evaluation.) Thus, adopting the SSM as a value never to be exceeded even in a large data set would be more protective than the human health risk-based geometric mean criteria and more protective than could have been envisioned by the Criteria Document authors. Adoption of the SSM as a value never to be exceeded is therefore not mandated by the BEACH Act requirement for State criteria "as protective" as EPA-published criteria.

**Organization Name:** Northeast Ohio Regional Sewer District

**Document ID:** 198

**Comment ID:** 305

**Comment:**

*Adoption of a never-to-exceed SSM would discourage more extensive sampling and have the unintended effect of reducing the level of protection..*

In support of a preference for applying the geometric mean criteria when implementing a risk-based approach for protecting human health, the Criteria Document states unambiguously, "It is the long-term geometric mean bacterial density that is of interest. Because of day-to-day fluctuations around this mean, a decision based on a single sample (or even several samples) may be erroneous, i.e., the sample may exceed the recommended mean criteria even though the long-term geometric mean is protective, or may fall below the maximum even if this mean is in the nonprotective range."

Adopting the SSM as a value never to be exceeded could, in practical implementation, have the undesired effect of discouraging the collection of sufficient samples to calculate a representative geometric mean - the indicator of human health risk acknowledged by EPA to be much superior to individual values from single samples. A State or local agency concerned about resource constraints could well ask, "Why collect five or more samples in a month when a single sample in a month is sufficient to determine attainment of the adopted standard?" Considering the Criteria Document's variability caution quoted above, adopting the SSM as a value never to be exceeded might thus, in many circumstances, result in less protection of human health.

Another instance of diminished human health protection likely to result from adoption of the SSM as a value never to be exceeded is described in Attachment B. The NEORSD is engaged in research intended to progress toward a predictive model to better protect the health of swimmers at local beaches. One aspect of this work, related to wave action and bacteria release from the sand, requires intensive sampling during periods when bacteria levels are anticipated to be high. Application of the SSM as a value never to be exceeded has unfortunate implications for this work. A final rule with this provision would penalize this work and discourage the very objective of public health protection that is the driving force behind both the standard and our current research. Therefore, in the interest of better providing protection for public health by not discouraging research, the proposed application of the SSM as a value never to be exceeded should be deleted from the final rule.

**Organization Name:** Northeast Ohio Regional Sewer District

**Document ID:** 198

**Comment ID:** 306

**Comment:**

Finally, adoption of the SSM as a value never to be exceeded could necessitate the selection of sewer separation for CSO control as the only long-term control plan option assuring that CSOs

are not causing or contributing to the SSM being exceeded. This would, however, have the unintended effect of increasing the risk to public health. NEORS studies have shown that sewer separation produces a total annual loading of bacteria and other pollutants to receiving waters that exceeds that resulting from other CSO control options. Much of the combined sewers' capture for treatment of storm water, also a major source of these pollutants, is lost through sewer separation's elimination of the combined sewer system. Pollutant loads that would have received treatment in a combined system are instead conveyed through separate storm sewers directly to the receiving waters without treatment. Because a resultant increase in total *E. coli* loading would produce an increase in the geometric mean *E. coli* density in the receiving waters, the associated human health risk would also increase.

***Criteria Document statements do not necessitate never-to-exceed SSM adoption.***

The Criteria Document states, "Noncompliance with the criterion is signaled when the maximum acceptable geometric mean is exceeded or when any individual sample exceeds a confidence limit, chosen accordingly or to a level of swimming use." A conclusion - notwithstanding the above-expressed concerns regarding level of human health protection - that this statement nonetheless necessitates adoption of SSMs as values never to be exceeded would be a misinterpretation.

A "signal" is typically defined as "something that incites to action" and "something that conveys notice or warning." The "action" incited could be an increase in sampling frequency or a beach closure; the "notice or warning" conveyed could be a beach advisory to avoid swimming. Considering the well-recognized extreme variability of bacteria levels in surface waters, such applications would be much more appropriate uses of the SSM than its adoption for determination of standards attainment under the Clean Water Act. The use of the term "signaled" is not synonymous with the term "determined" here. State adoption of the SSM as a value never to be exceeded for determining water quality standards attainment is not mandated by this statement in the Criteria Document.

**Organization Name:** Pennsylvania Department of Environmental Protection

**Document ID:** 233

**Comment ID:** 248

**Comment:**

Multiple issues, such as potential cut-offs or other considerations to address wet weather limitations on interpretation of bacterial impairments of uses, are important aspects in promulgating the criteria. Individual states and interstate agencies, such as the Ohio River Water Sanitation Commission (ORSANCO), are struggling to find workable means to account for the effects of weather conditions on bacteria densities, and this proposal ignores these important issues. Applying these regulations could have unintended results, extending the number of apparent impairments to waters; rather than provide a tool to more accurately account for real world conditions. Listing waters as impaired necessitates development of TMDLs, a resource-intensive task that diverts precious dollars from real problems.

**Organization Name:** Pennsylvania Department of Environmental Protection

**Document ID:** 233

**Comment ID:** 256

**Comment:**

Among the options for adoption of forms of the criteria, we believe that the geometric mean is the best expression of the criteria to be used in attainment of use decisions. Furthermore, because nonattainment is a long-term condition, we believe that long-term data are necessary to make that decision. We, therefore, support use of at least one full swimming season - in Pennsylvania that means six months - of data to judge that attainment. The geometric mean is also most useful in developing NPDES permitting limits, and the 1986 bacteria criteria document used the seasonal geometric mean as the basis for the correlation to the criterion.

We support not adopting the single sample maximum (SSM) as part of the DEP water quality standards for the state. The maximum or SSM value has merit for immediate, short-term decision making relating to opening or closing a beach on a particular day, and is appropriately adopted into the DOH beach regulations. PA DEP supports the approach where SSMs would be used to trigger decisions on beach advisories or closings or additional monitoring, but would not be used alone to determine nonattainment of the water quality standards. SSMs should be limited for use as an implementation tool for making decisions on beach advisories, closings, and additional monitoring.

If, however, single-sample maximums are including in the promulgation as part of the water quality standards, it must be clearly identified as to how the SSMs are to be used for beach-related decision making, only.

**Organization Name:** South Carolina Department of Health and Environmental Control Bureau of Water

**Document ID:** 161

**Comment ID:** 218

**Comment:**

**Issue: The use of single sample maximums (SSMs) in water quality standards and their implementation.**

The language used by the EPA in this notice is far different from that used previously in the draft implementation guidance. From this notice, it appears that the EPA is saying the SSMs should not be used in permitting activities, but only as a measure for beach closures. This is completely contrary to the way this issue has been discussed by the EPA previously. We maintain that the bacteria standard should have two parts: a geometric mean to be used as a chronic number in water quality programs and an SSM to be used as an acute number.

**Organization Name:** South Carolina Water Quality Association

**Document ID:** 200

**Comment ID:** 15

**Comment:**

First, we are opposed to EPA mandating the adoption of the upper percentile values in the 1986 criteria document. We believe the geometric mean is the appropriate regulatory requirement. We are not opposed to EPA authorizing states to choose and use upper percentile values where data to calculate the geometric mean are not available or where the UPVs are used in an advisory (i.e., non-regulatory) capacity.



**Organization Name:** South Carolina Water Quality Association

**Document ID:** 200

**Comment ID:** 17

**Comment:**

Second, regardless of what standard EPA chooses to impose in the final rule, EPA should follow its November 2003 guidance and make clear that for attainment, TMDL, and NPDES permitting purposes, only the geometric mean should be applied (again, where there is at least four samples during each month).

**Organization Name:** State of Alaska Department of Environmental Conservation/Division of Water

**Document ID:** 175

**Comment ID:** 154

**Comment:**

**Proposed Criteria for Pathogen Indicators: Use of the Single Sample Maximum.**

EPA requests comments on use of the geometric mean (GM) and single sample maximum (SSM) values. While EPA is proposing to promulgate criteria in both GM and SSM terms, we suggest that the 1986 data and analysis will only support an actual criterion expressed as a GM. As the discussion points out, the 1986 criteria document discusses SSMs solely in the context of beach closures and not in terms of establishing water quality standards. Consequently, the rule should include a specific criterion expressed as a GM for the purpose of assessing attainment with water quality standards and for taking Clean Water Act (CWA) actions such as issuing permits or developing Total Maximum Daily Loads (TMDLs). The rule might also allow states to incorporate SSM values into their criteria or as a basis for making beach closure decisions at their discretion. We suggest that this approach represents the most accurate interpretation of the 1986 guidance.

**Organization Name:** State of Connecticut Department of Environmental Protection

**Document ID:** 244

**Comment ID:** 161

**Comment:**

With regard to interpretation of the single sample maximum criterion (SSM), Connecticut strongly endorses the alternative option proposed: allowance for exceedance of the SSM when making attainment decisions. The SSM represents a statistically derived upper confidence limit on a steady-state geometric mean value associated with a stated risk of illness. For this reason, there should be a recognition incorporated into the assessment process that individual sample results will exceed this value. For high use areas, the frequency of excursions due to expected variability in the sampling data will be an unacceptably high 25% at monitoring locations where the geometric mean concentration is consistent with the geometric mean criteria. Connecticut supports an interpretation that SSMs would be used only for purposes of making beach closure/opening decisions (for which the SSM is appropriate) and not for assessment purposes (for which the SSM is ill suited).

**Organization Name:** State of Hawaii Department of Health/Environmental Health Administration

**Document ID:** 195

**Comment ID:** 395

**Comment:**

Geometric mean: Assuming that there must be a geometric mean beyond 300 meters/1000 feet and given that EPA will adopt criteria for Hawaii, DOH does not propose different enterococcus criteria from EPA's proposal of 33 CFU/100 ml for inland waters and 35 CFU/100 ml for open coastal or oceanic waters. DOH refers to its comments on waters to be covered, item 3 above, and to the attached response to public comments on the proposed DOH rules.

**Organization Name:** State of Hawaii Department of Health/Environmental Health Administration

**Document ID:** 195

**Comment ID:** 397

**Comment:****Single Sample Maximum status:**

We favor using a SSM as part of a water quality standard rule, and not just for decision making or as an implementation tool. DOH reserves its right to use secondary or supplemental indicators and other factors in making decisions.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 348

**Comment:**

Single sample maximums should not substitute for use of the geometric mean.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 349

**Comment:**

Single sample maximums should represent their related frequency of occurrence.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 365

**Comment:**

In addition to the likelihood that the geometric mean criteria are faulty for our state, the use of a confidence level to represent a single sample maximum is problematic. Statistically, if the data set used to derive the standard deviation is correct then the selection of a confidence interval to represent the single sample maximum ensures that with sufficient data collection even a site meeting the geometric mean will eventually have a sample collected that violates the single sample maximum. EPA is creating a 5 to 25 percent chance that an individual sample would be viewed in violation when, in fact, the water body is actually in compliance with the geometric mean. A single sample limit should only be included for use where the sample data set includes less than 10 samples. Were the data set is greater than 10 samples, then it would be appropriate to establish a 10 percent exceedence rule. For example, our freshwater standards read "Fecal coliform organism levels must not exceed a geometric mean value of 50 colonies/100 mL, with not more than 10 percent of all samples (or any single sample when less than ten sample points

exist) obtained for calculating the geometric mean value exceeding 100 colonies/100 mL." This approach incorporates the statistics in a simplified and manageable manner directly in the compliance evaluation.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 369

**Comment:**

Criteria should be designed to encourage monitoring sufficient to calculate the geometric mean, rather than to discourage it. The current proposal as well as many of the alternatives presented in this discussion does just the opposite. Any state that wants to minimize 303(d) listings and other compliance issues can rely on just the single sample maximum. With minimal sampling frequency, and some minor state level policies established on exceedence frequencies considered indicative of impaired waters, few (if any) waters would actually need to meet the geometric mean. If the motivation for the federal rule is EPA's concern over the level of protection provided, then the rule must ensure that some standardized level of protection would actually occur consistently between the affected states.

The use of confidence levels as single sample maximum limits is also a flawed concept by itself. Statistically, if a sufficient sampling program occurs, any water body that meets its geometric mean will occasionally exceed the single sample maximums that were based on that waterbody's standard deviation. Triggering a more comprehensive examination would make more sense than to use the single sample for any regulatory purpose. Using the single sample to close beaches would also make a little more sense, but neither closing beaches nor triggering follow-up monitoring is appropriate in rivers or marine waters that flush themselves over periods of less than a day. Until truly rapid analysis methods are established, responding to single sample events the next day makes very little sense. We really need to be looking and reacting to the long-term health of these waters.

An additional issue that has not been demonstrated by EPA is the effect of the high concentration periods on the overall illness rates that occurred over the summer season in their bather studies. It has not yet been demonstrated whether higher daily average bacterial concentrations accounted for most of the illnesses. If they did, then establishing a single sample maximum limit based on the seasonal standard deviation about the geometric mean may not be reasonably protective of public health. The public is probably unaware that the EPA criteria are based on restricting the total illness rate over the summer, rather than providing them with safe water during their visit to the beach. It is troubling that neither the states nor EPA seem to know what the variability in the incidence rates are in association with the EPA criteria. It is very likely that some moderate percentile of the total seasonal samples should also be below the national geometric mean criteria to be able to truly take the position that public health is being adequately protected.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 370

**Comment:**

The phrase "as protective of human health" needs to be interpreted broadly, but a federal rule needs to ensure that the impact would not be significantly different between affected states. Thus, allowing significant fluctuations in how the geometric mean is applied would be inappropriate. Moreover, the phrase "as protective of human health" needs to recognize how implementation

occurs in individual states. The same number applied in very different ways produces variable levels of protection.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 372

**Comment:**

The focus should remain on gaining compliance with the geometric mean, and any use of the standard deviation should really be based on ensuring the shape of the distribution. For example, Washington's freshwater bacteria standard is written as follows: "Fecal coliform organism levels must not exceed a geometric mean value of 50 colonies/100mL, with not more than 10 percent of all samples (or any single sample when less than ten sample points exist) obtained for calculating the geometric mean value exceeding 100 colonies/100 mL." This approach incorporates the statistics in a simplified and manageable manner directly in the compliance evaluation. The state further includes directives to collect and average multiple samples at swimming areas on each visit, and to not average data collected beyond a single season. These steps ensure that most of the time the water will remain within the geometric mean and that healthy water will be provided to our citizens.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 375

**Comment:**

Adding to this is the reality that EPA will not be examining every permit. We think that EPA has made an error in judgment in stating their confidence on the use of the single sample maximum criteria. It is less than clear, however, exactly how EPA or a state would be using the 75 or 95 percent confidence level when developing TMDLs or permits. What is the point of compliance? What is the averaging period? Is it based on the 75 percent of the hourly concentrations, daily concentration, or seasonal geometric means?

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 444

**Comment:**

If EPA continues towards finalizing the federal rule, it should restrict the focus only to designated bathing beaches to match the focus of the Beaches Act. EPA itself has opened the door to interpreting their national criteria recommendations as perhaps being applicable only at designated beaches. Consistent with this revised focus, EPA should include more common sense requirements on monitoring and notification as well as on general sanitation programs that reduce the risk of outbreaks. Clean and adequate restrooms, separate bathing areas for toddlers, vending machines with swim diapers, education kiosks on swimmer-to-swimmer disease transmission, etc. are all examples of programs that would likely result in greater overall protection than the current EPA rule will accomplish.

Without specific directives to ensure that adequate sampling would occur, or that the geometric mean would be the focus of state regulatory programs, even the apparent EPA goal of state-to-state consistency will not occur in response to this federal rule.

**Organization Name:** The CSO Partnership

**Document ID:** 197

**Comment ID:** 404

**Comment:**

EPA Must Use this Opportunity to Provide a Clear Statement on the Application of the Bacteria Criteria

Almost 20 years after EPA's 1986 criteria were published, this rulemaking will be EPA's best chance to present a clear and consistent explanation of how those criteria are intended to be applied. We are disappointed that after no less than three public comment periods on EPA's implementation guidance and the opportunity of this draft rule, EPA still has not clearly and definitively resolved a number of fundamental questions about these criteria. Give this uncertainty and these delays by EPA, the states have been hindered in their ability to move toward the adoption of these standards. In our view, EPA must use the opportunity of this rulemaking to definitely establish the geometric mean as the regulatory requirement from the 1986 criteria.

**Organization Name:** The CSO Partnership

**Document ID:** 197

**Comment ID:** 405

**Comment:**

**"Single Sample Maximums"**

At the outset, we are surprised that EPA chose to return to the use of the term "single sample maximum" ("SSM") to describe what we understand the Agency had correctly defined as "upper percentile values" (UPVs) in its November 2003 guidance on implementing the 1986 bacteria criteria.<sup>1</sup> EPA went so far in its 2003 guidance to state that "The 'single sample maximum' was never intended to be a 'value not to be exceeded' when referring to attainment decisions and National Pollutant Discharge Elimination System (NPDES) permitting under the Clean Water Act. Therefore, EPA is dropping the use of the term in favor of the more statistically correct term 'upper percentile value.'"

EPA started its criteria document by calling these values "confidence intervals" in its original Federal Register notice, then "confidence levels" in the actual criteria document, and now has flip-flopped between SSMs and UPVs.

We fail to understand why EPA would not stick with the UPV clarification in today's proposed rule. To prevent further confusion among stakeholders, we urge EPA to stick to its decision to drop the use of the "SSM" term in favor of the exclusive future use of the more "correct term" "UPV."

**Footnote:**

<sup>1</sup>EPA explained in that guidance: "The term 'upper percentiles' is used in place of 'single sample maximum' to more accurately reflect their derivation and more adequately reflect the range of recommended usage of this aspect of EPA's criteria." EPA November 2003 Bacteria Guidance at Section 1.5.

**Organization Name:** The CSO Partnership

**Document ID:** 197

**Comment ID:** 406

**Comment:**

The Beach Act Only Requires the Adoption of the Geometric Mean.

Because the 1986 bacteria criteria were developed around the geometric mean and because the geometric mean has the most direct relationship to the illness rate, the best interpretation of the Beach Act is that only the geometric mean must be promulgated. How, or if at all, states decide to use the UPVs, is purely an implementation policy decision. The UPVs would be available for use as an implementation tool for making beach advisory decisions but would not be part of the applicable water quality standards. States and Territories would have the flexibility to use the UPVs in this or any other application of the water quality standards as they deem appropriate.

This is clearly the most rational approach and the one that we strongly recommend to EPA. The UPVs are simply not suitable for making regulatory decisions in our view. EPA should begin with the geometric mean-only approach and then in the highly unlikely event that there is a demonstrated need to impose the UPVs as a hard value, such an approach could be adopted in a subsequent promulgation.

We note that EPA enjoys broad discretion in interpreting its criteria document. Moreover, there is clearly no statutory requirement to impose UPVs given that sound reasons exist not to. Moreover, Section 304(a)(9) - added by the 2000 Act - expressly gives EPA five years to publish new criteria, "including a revised list of testing methods, as appropriate." This provision clearly authorizes EPA to make any appropriate refinements to the criteria before imposing them by federal rule. Thus, for the purpose of this rule, EPA should require only the geometric mean and leave to a future rulemaking the need to address any issues regarding the UPVS.<sup>2</sup>

Notably, imposing only the geometric mean criterion would provide an incentive requirement to collect more than a single sample. In this respect, such an option c

**Organization Name:** The CSO Partnership

**Document ID:** 197

**Comment ID:** 407

**Comment:**

**Any Upper Percentile Values Should Be Advisory Only - With the Possible Exception of Where Data are Lacking**

The draft rule proposes that States adopt UPVs (incorrectly referred to as "SSMs"). We are deeply concerned about how EPA intends for states to apply these criteria to:

- Impaired Waters (303(d) Assessment)
- Wasteload Allocations (WLA)
- Total Maximum Daily Loads (TMDL)
- POW, CSO and Stormwater NPDES permits.

EPA's proposed approaches to addressing the UPVs cover the spectrum from not adopting any at all, to leaving site-specific UPVs up to states to adopting a UPV only for designated beach waters.

EPA cannot ignore this critical issue by categorizing it as an "implementation matter" because in many states, EPA's criteria will be applied at the end-of-pipe for POTWs and other regulated sources. For example, Virginia, Maryland, Pennsylvania, the District of Columbia, West Virginia, North and South Carolina all impose EPA's bacteria criteria as end-of-pipe requirements in NPDES permits.

At the outset, using UPVs to make regulatory decisions is highly questionable given the strong likelihood of getting a high value somewhere in every recreational water from time to time. Such localized individual samples are not reflective of the overall water quality of a water body either at that instant or over time. EPA's own criteria document admits that "because of the day-to-day fluctuations around this mean, a decision based on the single sample may be erroneous."

Accordingly, our recommended approach is for EPA to adopt only the geometric mean and then require that enough samples are collected for assessment and NPDES purposes to allow a calculation against the mean. For bathing beaches, EPA could recommend that the UPVs be set by the individual states and used in an advisory manner rather than as the determinative factor

**Organization Name:** The CSO Partnership

**Document ID:** 197

**Comment ID:** 408

**Comment:**

Finally, we agree with EPA that in no case should UPVs be interpreted as "Never to be Exceeded" values for any purpose, except where there is inadequate data to calculate a geometric mean. Even then, the best approach outside of designated beaches should be follow-up monitoring to allow assessment against the geometric mean rather than attaching any regulatory significance to a single high value. The final rule should expressly re-state this critical limitation on the use of any UPVs.

**Organization Name:** The CSO Partnership

**Document ID:** 197

**Comment ID:** 409

**Comment:**

**Regardless of the Standards, EPA Should Clarify that the Geometric Mean Should be Used for Attainment and NPDES Purposes**

To address the assessment, TMDL, WLA and permitting issues we recommend the following language be included in the final rule:

"Where adequate data are available, only the long-term geometric mean value shall be used for the purposes of

- Assessing attainment of Water Quality Standards
- Developing Total Maximum Daily Loads
- Establishing Waste Load Allocations and
- Developing WQBELs for NPDES permits"

This language is fully consistent with EPA's November 2003 implementation guidance for the bacteria criteria. Among several reiterations of the point in EPA's guidance is the following quote:

"EPA recommends that states and authorized tribes use only the geometric mean component for NPDES water quality-based effluent limits."

Guidance at 4.2.2.

The Commonwealth of Virginia, among other states, has been implementing this type of approach for some time now. The Virginia Department of Environmental Quality has imposed requirements that the UPV is used for NPDES purposes where there is only one sample result but the more accurate geometric mean is used whenever there is enough data to calculate a geometric mean. Virginia DEQ Guidance Memo Number 03-2007, Implementation of Bacteria Standards in VPDES Permits (see <http://www.deq.virginia.gov/>).

**Organization Name:** The CSO Partnership

**Document ID:** 197

**Comment ID:** 417

**Comment:**

We are seriously concerned about several aspects of the proposed rule, with our greatest concern being the potential misuse of the SSMs/UPVs. It is essential that EPA either adopt only the geometric means from the 1986 criteria or if the UPVs are also to be included, that they are qualified so that only the geometric mean will be used for attainment, TMDL, and NPDES permitting purposes.

**Organization Name:** The City of New York Department of Health and Mental Hygiene

**Document ID:** 239

**Comment ID:** 138

**Comment:**

**Use of the Single Sample Maximum:**

EPA is proposing the use of all four single sample maximum (SSM) values in the 1986 bacteria criteria document for the proposed rule. EPA recognizes that many states have issues concerning the interpretation and implementation of SSM values. In advancing the merits of the proposed approach, EPA elaborates on the value and interpretation of SSM, identified four management alternatives, and solicits comments on these options.

*(1) Apply as a single sample value never to be exceeded. (Citation from page 41725, Federal Register, Vol. 69, No. 131, July 9, 2004/Proposed Rules)*

**Comments:** As shown on Table 1 for marine waters<sup>1</sup>, a geometric mean density of 35 per 100 ml is the enterococci criterion value associated with an acceptable illness rate of 19 per 1,000 swimmers. This table is the basis for the criteria in the proposed rule. Table 1 also shows a series of "single sample maximum allowable density" values at the 75<sup>th</sup>, 82<sup>nd</sup>, 90<sup>th</sup> and 95<sup>th</sup> percent upper confidence limits (CL). These values are selected arbitrarily, but not necessarily unreasonably, from the probability (frequency of occurrence) distribution for enterococci, which EPA derived for the illness rate based on field data. This distribution is shown on Figure 1. The single sample maximum values shown on Table 1 are intended to indicate that non-compliance with the



geometric mean is "signaled" by an unacceptably high value for any "single bacterial sample," the value of which is related to intensity of recreational use as shown on Table 1.

The geometric mean (GM) represents the central tendency of a series of datapoints and is considered to be the statistical method of choice when interpreting a series of bacterial measurements taken over a period of time. "In contrast, a single sample with a high value does not necessarily indicate that the waterbody as a whole has high bacterial levels" (Citation from page 41722, Federal Register, Vol. 69, No. 131, July 9 2004/Proposed Rules). This is especially true when the majority of sample results are under SSM. The proposal of having "the SSM as a value not to be exceeded," has little, if any, statistical merit. It is observed from Figure 1 that individual sample values as high as 100 to 1,000 per 100 ml or so may be observed in a series of data with a geometric mean of 35 per 100 ml. The adoption of SSMs never to be exceeded will clearly result in our being overly protective, and will: 1) cause unnecessary beach closures; 2) require regulatory action which may be more restrictive than is necessary for the protection of public health; and 3) adversely impact public perception and the local economy. Therefore, the GM should be the only water quality parameter that regulatory agencies should be required to use as the water quality standard for beach closure actions. The criteria document is clear in that illness was not related to individual measurements of enterococci density, but rather to the geometric means of a series of samples. It is therefore the geometric mean of 35 per 100 ml from a series of samples, which is related to the illness rate of 19 per 1,000 swimmers and not to individual sample values.

**Footnote:**

<sup>1</sup>USEPA. 1986. Ambient Water Quality Criteria for Bacteria-1986. EPA-440/5-84-002.

**Organization Name:** The City of New York Department of Health and Mental Hygiene

**Document ID:** 239

**Comment ID:** 139

**Comment:**

*Allow for exceedence of the SSM when making attainment decisions. Under this option, an unacceptably high value for any individual sample may be used to trigger a beach advisory, closing or additional monitoring, or it might be evaluated with other sample results, but would not necessarily be used alone to determine nonattainment of the water quality standards. (Citation from page 41725, Federal Register, Vol. 69, No. 131, July 9, 2004/Proposed Rules)*

This is a better alternative to the use of an SSM as a value never to be exceeded. However, when an adequate monitoring program is available, the final rule should not require that an exceedance of an SSM trigger mandated regulatory action (advisories, closings or additional monitoring as EPA suggests) but rather serve as an alerting value to the regulatory agencies that an evaluation and potential re-sampling and reassessment is warranted. SSMs should be viewed and used solely as an operational tool by local health departments and beach operators.

**Organization Name:** The City of New York Department of Health and Mental Hygiene

**Document ID:** 239

**Comment ID:** 140

**Comment:**

*SSMs would be part of the water quality criteria, but only used for making beach closure and opening decisions. States and Territories could use only the geometric mean for other CWA purposes such as NPDES permitting, TMDLs and waterbody assessments. EPA may decide to*

*include an explicit interpretation or definition of the SSM in the final regulatory text. (Citation from page 41725, Federal Register, Vol. 69, No. 131, July 9, 2004/Proposed Rules)*

This is the most desirable alternative among the four proposed alternatives, providing EPA explicitly interprets and/or defines the SSM as a discretionary management tool where satisfactory monitoring data are available. Use of the GM for beach opening and closing decisions will minimize the effect of single high measurements that would otherwise be considered outliers. The GM statistical method has the most direct relationship to risk and is essential in determining more representative long-term water quality conditions, especially chronic pollution, when a sufficient number of samples have been taken over the course of the recreational season. Frequent exceedences of the GM criterion of 35 per 100 ml for marine water will likely be indicative of the existence of chronic contamination. SSM values should only be viewed and used as an operational tool or guide for making decisions for public notifications, nothing more, when sufficient monitoring data are available. "Geometric Mean" values should be used both as the water quality criterion for beach closure actions and TMDL determinations, an approach that has scientific validity and is, therefore, legally defensible.

We believe that many local regulatory authorities have sufficient information to make scientifically reliable determinations and take correct regulatory actions, even if individual SSM exceedences occur. For example, local authorities can use the following tools to make a determination of statistical significance for a measured single sample exceedance: 1) on-going trends based on data collected from regular water monitoring and sample collection (often begun prior to the bathing season); 2) historical water quality data for the general ambient conditions, and probability distributions; 3) reports of pollution events from other regulatory agencies; and (4) practical knowledge of exogenous factors affecting the beach waterbody. Our Departments and many regulatory agencies have the aforementioned information available for contemporaneous evaluation.

If this alternative is adopted and SSMs are specified as water quality criteria, EPA must provide clear interpretation and/or definition of the SSMs as management guidance tools only to be used by regulatory authorities at their discretion when sufficient monitoring data are available. We believe that it would be beneficial to re-designate the term SSM to "Single Sample Value" (SSV) from "Single Sample Maximum" to avoid misinterpretation

**Organization Name:** The City of New York Department of Health and Mental Hygiene

**Document ID:** 239

**Comment ID:** 141

**Comment:**

*EPA would promulgate only the geometric mean in the final rule. The SSMs would be available for use as an implementation tool for making beach opening and closure decisions but would not be part of the applicable water quality standards. States and Territories would have the flexibility to use the SSMs in this or any other application of the water quality standards, as they deem appropriate. (Citation from page 41725, Federal Register, Vol. 69, No. 131, July 9, 2004/Proposed Rules)*

The technically appropriate element of this alternative is the promulgation of the GM in the final rule which would therefore serve as a required baseline criterion for recreational water use, NPDES permitting, TMDLs and waterbody assessments. However, by providing absolute flexibility to States and Territories to use the SSMs as they deem appropriate, there is the risk that some jurisdictions may apply the SSM values for the various regulatory actions cited above

which would not be technically defensible. Consequently, we believe that it is more beneficial for EPA to propose a rule for national application with clear definitions: the GM to be used for beach opening and closing decisions, TMDLs and other regulatory requirements, and SSMs as discretionary operational tools for use by beach regulatory agencies when sufficient monitoring data are available.

**Organization Name:** The City of New York Department of Health and Mental Hygiene

**Document ID:** 239

**Comment ID:** 143

**Comment:**

As discussed above with regard to the application of SSMs, we believe that EPA's alternative interpretation number 3 comes the closest to being the technically defensible application of EPA's criteria document for bacteria and insures cost-effective protection of the public health and safety.

**Organization Name:** The City of New York Department of Health and Mental Hygiene

**Document ID:** 239

**Comment ID:** 144

**Comment:**

The main points that we recommend for your consideration are as follows:

1. The SSM values cited in the 1986 criteria document should be clearly defined in the proposed rule such that, when sufficient monitoring data are available, they are not to be considered as values never-to-be-exceeded but rather they are to be used as alerting values to regulatory agencies that an evaluation and potential re-sampling and reassessment is warranted at their discretion.

**Organization Name:** The City of New York Department of Health and Mental Hygiene

**Document ID:** 239

**Comment ID:** 145

**Comment:**

The GM value should be used as the water quality criterion for beach opening and closing decisions when sufficient data are available. In addition, the GM value should be used for TMDL determinations, NPDES requirements and waterbody assessment purposes.

**Organization Name:** The City of New York Department of Health and Mental Hygiene

**Document ID:** 239

**Comment ID:** 147

**Comment:**

The SSM should be re-designated as "Single Sample Value" (SSV) from "Single Sample Maximum" to avoid misinterpretation.

**Organization Name:** The City of New York Department of Health and Mental Hygiene

**Document ID:** 239

**Comment ID:** 148

**Comment:**

For purposes of beach management, it is recommended that the EPA consider the application of the geometric mean of 35 per 100 ml to varying flexible durations (e.g. less than 30 days), depending upon local conditions, when sufficient numbers of samples are collected. The application of a geometric mean for a period less than 30 days would not be applicable to TMDL, NPDES, etc.

**Organization Name:** Tri-TAC

**Document ID:** 223

**Comment ID:** 428

**Comment:**

Tri-TAC offers the following comments for your consideration.

The proposed steady state geometric mean indicator density of 35/100 ml of enterococci for marine waters is scientifically defensible for Southern California marine waters influenced by storm drain outlets as demonstrated by the Santa Monica Bay Restoration study.<sup>1</sup> Although this study defined an acceptable risk level in a different fashion from that discussed in EPA's proposed rule, the results are consistent with EPA's end result. The Restoration Study looked at relative risk levels to swimmers relatively closer and farther away from a source of pathogen contamination and used relative risk to confirm EPA's proposed geometric mean indicator density of 35/1100 ml of enterococci for local ocean waters as the concentration that increased swimmer illness. This is the same standard adopted by the California Department of Health Services in the California beach sanitation standards and the Los Angeles Regional Water Quality Control Board water quality objectives for ocean waters, and it is the same as the recommendation in the proposed amendments to the California Ocean Plan.<sup>2</sup>

**Footnotes**

<sup>1</sup> Haile, R.W., Witte, J.S., Gold, M., Cressy, R., McGee, C.D., Millikan, R.C., Glasser, A., Harawa, N., Ervin, C., Harmon, P., Harper, J., Derman, J., Alamillo, J., Barrett, K., Mides, M., Guang-yu Wang (1999) "The Health Effects of Swimming in Ocean Water Contaminated by Storm Drain Runoff" *Epidemiology*, Vol. 10, Number 4:355-363.

<sup>2</sup> See Pages 22-23 of the Draft Functional Equivalent Document, Amendment of the Water Quality Control Plan Ocean Waters of California, State Water Resources Control Board, August 2004.

**Organization Name:** Tri-TAC

**Document ID:** 223

**Comment ID:** 429

**Comment:**

EPA solicited comment on the use of the Single Sample Maximum (SSM). Specifically, should the SSM be used as a single value never to be exceeded or, in the alternative, should EPA allow exceedances of the SSM when making attainment decisions because bacterial measurements are inherently variable? Tri-TAC supports the latter option, and proposes that high values for any given individual sample be used to trigger a beach advisory or closing or additional monitoring, or that such results be evaluated with other sample results, but not be used alone to determine attainment/nonattainment of the water quality standards. This approach is consistent with the proposed amendments to the California Ocean Plan, discussed above, which would use the SSM to trigger additional monitoring and, if necessary, a sanitary survey to determine the source of

contamination. The concentration of fecal indicator bacteria varies over time scales that span several orders of magnitude, from minutes to decades and is due to a complex combination of local and external processes. No single sample result is an indication of the overall water quality for a given water body.<sup>3</sup> The geometric mean standard is a much better indicator of the attainment or nonattainment of a specific water body for bacteria as it addresses the overall assessment of water quality.

**Footnote**

<sup>3</sup> Boehm, A.B., J.H. Kim, S.L. Mowbray, C.D. McGee, C.D. Clark, C.M. Foley, D.E. Wellman, S.B. Grant (2002) "Decadal and Shorter Period Variability of Surf Zone Water Quality at Huntington Beach, California" Environmental Science and Technology 36:3885-3892.

**Organization Name:** William Hastback

**Document ID:** 157

**Comment ID:** 451

**Comment:**

EPA indicates that the new proposed enterococcus standards will have both geometric mean and upper limit components, perhaps a 75th or 90th percentile. In the Draft Review, EPA does not specify the statistical method that would be used for calculating the estimated the 75th or 90th percent value from the existing data set. There are different methods for doing that.

**Organization Name:** Wisconsin Department of Natural Resources

**Document ID:** 176

**Comment ID:** 109

**Comment:**

The Section agrees with the alternative option for use of the single sample maximum (SSM) in Section III. B. 1. titled, *Use of the Single Sample Maximum*. In this option EPA is proposing that the SSM be used to trigger a beach advisory or closing but not necessarily be used alone to determine nonattainment of the water quality. SSM results can be quite variable due to a number of factors and these results may not reflect the underlying water quality. We agree that the 1986 bacteria criteria document discusses SSMs solely in the context of beach closures and should not be used for other CWA purposes, such as NPDES permitting, TMDLs and waterbody assessments. Instead, only the geometric mean should be used for those purposes. Since, in the 1986 study, the geometric mean was correlated with the average gastrointestinal illness rate and has the most direct relationship to the illness rate, we agree that EPA should promulgate only the geometric mean in the final rule.

**Response:**

See the preamble to today's rule, in particular section IV.B.3., Use of the Single Sample Maximum.

Several commenters suggested renaming single sample maximums to some other term. EPA declines to make this change in order to remain consistent with the terminology in EPA's 1986 bacteria criteria.

## **Issue: SSM 1**

**Organization Name:** County of Orange, CA/RDMD/Watershed and Coastal Resources Division

**Document ID:** 193

**Comment ID:** 182

### **Comment:**

Recent research by the University of California, Irvine, supported by the County of Orange, on coastal bacteria problems in Orange County has resulted in several papers being published in the journal Environmental Science and Technology. We strongly encourage the EPA to review these, in particular an article entitled "Public Mis-Notification of Coastal Water Quality: A Probabilistic Evaluation of Posting Errors at Huntington Beach, California", Joon Ha Kim and Stanley B. Grant, Environ. Sci. Technol.; 2004; 38(9) pp 2497 - 2504, which discusses the beach posting errors inherent in using single samples.

### **Response:**

EPA appreciates the suggestion from the commenter to review the article. However, EPA believes that the findings in this article speak to the difficulty of assessing water quality at beaches without consistent monitoring that utilizes rapid testing methods. It does not claim that beach posting errors are solely due to using single samples.

## Issue: SSM-Site Specific

**Organization Name:** Buckeye Florida

**Document ID:** 172

**Comment ID:** 240

**Comment:**

*State Calculation of Site-specific SSMs* - Again using the geometric mean only approach for the water quality criteria will preclude EPA from needing to specify this. Buckeye supports the Florida approach related to validated data as articulated in the Florida Impaired Waters Rule. Florida and other states should be allowed to continue their respective application of data validation requirements to this bacterial standard.

**Organization Name:** New Jersey Department of Environmental Protection

**Document ID:** 178

**Comment ID:** 25

**Comment:**

**The proposal to require 30 or more samples for a single recreation season to establish a site-specific standard deviation (p. 41727).**

New Jersey supports the recommendation that 30 or more samples should be collected to calculate a site-specific standard deviation. However, New Jersey does not collect 30 samples at any of its ~ 350 designated ocean and bay bathing beaches during a single season as it does not have the resources to do so. Hence, New Jersey would not be able to calculate site-specific standard deviations according to this proposal. However, the type and extent of pollution entering New Jersey waterways is not significantly different over the course of any 2-year period and New Jersey does collect 30 or more samples at each site over a 2-year period. There is no reason why this collection period could not be extended to 2 years to calculate site-specific data standard deviations using 30 or more samples. As stated above however, the calculated site-specific standard deviations should only be used to calculate the site-specific 75% upper CI value (*i.e.*, designated beach SSM) for beach closure decision purposes.

**Organization Name:** South Carolina Department of Health and Environmental Control Bureau of Water

**Document ID:** 161

**Comment ID:** 222

**Comment:**

**Issue: Site-specific standard deviations.**

Understanding that any site-specific standard deviation based on data collected in a specific waterbody would most likely have some, if not significant, anthropogenic sources of bacteria, how would EPA allow a state to set those values based on such data? For instance, State A has a waterbody that often has a "higher" bacteria value in an area where nonpoint source controls are poorly maintained. This occasional high value would then be included in the data and used to establish the standard deviation, this would mean that the supposedly protective 75<sup>th</sup> percentile would allow at least some "cushion" for those anthropogenically induced higher values and allow recreational users to be put at a higher risk, not because of natural conditions, but because State A was unwilling to maintain BMPs. The EPA needs to make sure that if site-specific standard deviations are used, they exclude contributions from anthropogenic sources.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 361

**Comment:**

EPA should also consider the implementation programs used by states as compared to the federal recommendations. A state that uses monthly sample data to calculate the geometric mean during the summer period should be viewed differently than one that has adopted the policy of not calculating the geometric mean unless five samples per month have been analyzed - all but eliminating the general use of the more protective geometric mean.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 380

**Comment:**

We have found that bacterial concentrations do not tend to be highly variable at individual sampling sites in large water bodies such as our coastal and marine waters or in our more pristine streams. It is important to recognize that variability is more the result of the variable inputs of bacterial substances, and high variability is typically a characteristic of polluted waters. We have previously explained our concerns with the use of a site adjusted single sample maximum. Using the probability statistic to trigger a regulatory action may actually be made more problematic if it is based on site-specific data. If the exceedence frequency is made more accurate, then the probability of assuming a problem when one doesn't actually exist is even more likely to occur at that given frequency.

**Organization Name:** Tri-TAC

**Document ID:** 223

**Comment ID:** 430

**Comment:**

Tri-TAC supports the use of State Calculation of Site-Specific SSMs. This approach allows States to consider both the inherent variability of local waters as well as an assessment of site-specific beach usage. A minimum sample size of 30 is appropriate to determine a site-specific standard deviation used to calculate the SSM.

**Response:**

See the preamble to today's rule, in particular IV.B.6., State Calculation of Site-Specific Single Sample Maximums.



## Issue: Scope of the Rule

**Organization Name:** Association of Metropolitan Sewerage Agencies

**Document ID:** 227

**Comment ID:** 288

**Comment:**

*Application in CSO-Receiving Waters*

AMSA also recommends that EPA clarify the applicability of the final rule in combined sewer overflow (CSO) impacted waters. Implementation of water quality standards for CSO-impacted waters is covered by the Wet Weather Water Quality Act of 2000 (CWA Section 402(q) and the 1994 CSO Policy). Based on the provisions of that law we recommend the following language be included in the rule:

"For CSO impacted waters, compliance with these water quality standards shall be assessed following implementation of an approved long term control plan in accordance with the *CSO Control Policy*."

**Organization Name:** Chesapeake Bay Foundation

**Document ID:** 231

**Comment ID:** 167

**Comment:**

In sum, the deficiencies in the Pennsylvania program make the citizens of the Commonwealth vulnerable to public health and water quality problems associated with pathogen contamination. CBF is concerned that while the proposed policy will result in increased environmental protection for the small portion of Pennsylvania's Great Lakes area, the remainder of the Commonwealth's 83,131 miles of stream and 161,445 acres of lakes will not be awarded such protection.

**Organization Name:** Department of Environmental Services City and County of Honolulu

**Document ID:** 235

**Comment ID:** 300

**Comment:**

Section 131.41(c)(2)

The proposed regulations do not address where the criteria would apply in the water column. We feel that in deeper waters, i.e. deeper than say 150 feet, the criteria should apply to only the surface because any primary contact activities would only occur on the surface. DOH should probably address this issue along with the determination of the primary contact activity zone.

**Organization Name:** Kansas Department of Health and Environment, Division of Environment, Bureau of Water

**Document ID:** 173

**Comment ID:** 195

**Comment:**

Although Kansas waters are not directly affected by the proposed rule, the rule does address some freshwater bacteria criteria. We are concerned the rule could ultimately be applied to all inland waters.

**Organization Name:** King County Department of Natural Resources and Parks

**Document ID:** 204

**Comment ID:** 469

**Comment:**

Also, we have freshwater lakes just inland of our coastal waters in Seattle, connected to the marine water by a locks system. These lake areas represent a major recreational resource and with this rulemaking EPA would be creating a two-tiered system of bacterial indicators with no significant reason for the difference.

**Organization Name:** New Jersey Department of Environmental Protection

**Document ID:** 178

**Comment ID:** 449

**Comment:**

Although, the Water Quality Criteria proposed in this rule specifically apply to coastal and Great Lake waters that are designated for swimming, bathing, and other similar activities for which States do not have EPA approved criteria in place, the decisions adopted by USEPA in the final rule may impact other States modifying existing water quality standards for bacteria.

**Organization Name:** New York State Department of Environmental Conservation

**Document ID:** 218

**Comment ID:** 85

**Comment:**

Final Rule Needs to Clearly Specify the New York Waters Included.

New York is diligently working to establish criteria that will result in the withdrawal of the federal rule. In order to achieve this, we need to know exactly which New York State coastal fresh and marine waters are included in the federal rule. For instance, where (exactly) does the USEPA draw the line at the mouth of the Hudson River such that waters upstream of this point are excluded from the rule?

**Organization Name:** Oregon Department of Environmental Quality

**Document ID:** 174

**Comment ID:** 58

**Comment:**

DEQ seeks clarification on whether the final rule will define "fresh water" and "marine water" with regard to the applicability of the criteria to estuaries or leave such definitions up to States. It is our understanding that if the proposed rule is adopted as final, DEQ would apply to bays and estuaries the freshwater criteria in water where freshwater and sea water are mixing and the marine criteria to waters equivalent to full-strength sea water. DEQ believes this is the best approach for protecting beneficial uses.

**Organization Name:** Pennsylvania Department of Environmental Protection

**Document ID:** 233

**Comment ID:** 255

**Comment:**

While our Commonwealth has opted for the expediency of adopting the newer criteria for bathing beaches in fulfillment of the Beaches Act requirements, we are reluctant to adopt the criteria for all our surface waters because of the uncertainties and unanswered questions that remain. Pennsylvania's main concerns have been the lack of approved analytical methods for the indicators in effluent matrices and absence of a complete guidance on implementation, particularly in wet weather situations. We also join the other states in urging EPA to address equally compelling concerns, such as human versus animal sources and scientific confidence in the criteria.

**Organization Name:** South Carolina Department of Health and Environmental Control Bureau of Water

**Document ID:** 161

**Comment ID:** 226

**Comment:**

The discussion of the alternatives and suggestions for implementation in the preamble to the rule are enlightening and certainly worthy of further discussion. However, we are concerned that if specific implementation procedures are included in a final rule they will become the expectation for implementation of all bacteria criteria in all states - much like the California Rule for Toxics.

**Organization Name:** State of Connecticut Department of Environmental Protection

**Document ID:** 244

**Comment ID:** 160

**Comment:**

The State of Connecticut, Department of Environmental Protection adopted EPA's 1986 recommended ambient water quality criteria for indicator bacteria in 1989. Currently these criteria provide the basis for monitoring and assessment of use attainment in all waters designated for recreational use and provide the basis for closure decisions at all state-owned bathing areas. Our interest in this matter stems from a concern that a precedent is being set by EPA's action that will be applied by EPA to interpretation of state's implementation of the indicator bacteria criteria for waters not specifically covered by the proposed regulation. Although EPA has stated that the proposed rule applies only to coastal and great lakes recreation waters, it is difficult to envision how protection of recreational uses in these waters differs in any fundamental way from protection of recreational uses in other waters subject to the provisions of CWA Section 303(c).

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 347

**Comment:**

All states should be brought into any federal rule aimed at beach protection.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 446

**Comment:**

We also find it unacceptable that EPA is using the Beaches Act to promulgate standards only on those states with coastal waters, given the high use of freshwater beaches in many non-coastal

states. EPA should not be forcing inequity between coastal and non-coastal states. Non-coastal states should also be brought into this federal rule if EPA believes their criteria are necessary to adequately protect water contact recreation. The Beaches Act does not prohibit EPA from bringing all states into compliance with their recommendations and EPA has a responsibility to take actions that do not establish different economic and social burdens between states without just cause. Such just cause has not been demonstrated in this case.

**Organization Name:** The CSO Partnership

**Document ID:** 197

**Comment ID:** 403

**Comment:**

Potential precedent for application of criteria nationwide.

While this rule would only apply on its face to coastal recreational waters, EPA should be mindful that the policy decisions made here are likely to set a strong precedent for application of the 1986 bacteria criteria to all waters designated for recreational uses nationwide. As we note below, this final rule will have major regulatory and financial impacts.

**Response:**

See the preamble to today's rule, in particular sections II.A.2., BEACH Act; II.B., 1986 Ambient Water Quality Criteria for Bacteria; and/or IV.A., Scope of the Rule.

In addition, because today's rule applies to coastal and Great Lakes waters designated by States and Territories for swimming, bathing, surfing, or similar water contact activities, the criteria apply to the entire water column unless the designated use only applies down to a certain depth.

EPA disagrees with the commenter's suggestion that EPA include explicit regulatory language regarding compliance with EPA's CSO Control Policy. EPA recognizes that, in CSO-impacted waters, municipalities will develop long-term control plans consistent with the CSO Control policy and the applicable water quality standards. Additionally, EPA recognizes that development and implementation of these plans can take several years. As described in the preamble to today's rule, in particular section IV.D., the CSO Control Policy allows for multiple enforceable mechanisms that provide municipalities with sufficient time to implement long-term control plans. Today's rule does not change that approach.

## Issue: Seasonal Uses

**Organization Name:** Michael Doran Techknowledge

**Document ID:** 209

**Comment ID:** 150

**Comment:**

Air and water temperatures in Wisconsin and other Great Lakes states preclude the use of the Great Lakes for body contact recreation at certain times of the year. The same may be the case for marine waters in certain northern states. Because recreational use does not reasonably exist at these times, in these locations, a provision should exist in the rule that allows states to exempt waters from compliance with the standards during the non-recreational season.

The following wording is recommended in Section 13.141 (c): "For waters which have been designated as recreational use waters, but where it can be shown by the State that recreational use is not reasonably practiced during certain times of the year because of low air and water temperatures that do not support such use, States may suspend the requirement for such waters, during such times, to be in compliance with the numeric standards contained in paragraph (c)(1) or (c)(2)."

**Response:**

Federal water quality standards regulations at 40 CFR 131.10(f) allow for seasonal uses, provided the criteria adopted to protect such uses do not preclude the attainment and maintenance of a more protective use during the recreational season. Several States and Territories have adopted, and EPA has approved, primary contact recreation and associated water quality criteria only for those months when primary contact recreation occurs and have relied on less stringent secondary contact recreation water quality criteria to protect for incidental exposure in the "non-swimming" season. With this rulemaking, EPA does not change States' and Territories' ability to adopt seasonal uses for their waters, including Great Lakes and marine waters. EPA declines to adopt the recommendation for regulatory text to suspend the water quality standards during certain times of the year because CWA section 303(i) applies to all coastal recreation waters designated by a state for swimming, bathing, surfing, or similar water contact activities, not just coastal recreation waters where swimming actually occurs.

## **Issue: South Carolina**

**Organization Name:** South Carolina Department of Health and Environmental Control Bureau of Water

**Document ID:** 161

**Comment ID:** 216

**Comment:**

South Carolina is a coastal state included in this proposed rulemaking. We have promulgated and our Legislature has approved the appropriate bacteria standards for our coastal recreation waters; they were submitted to EPA in July 2004 for approval. Although we expect to obtain approval and will not be included in the final rulemaking, we still have concerns regarding the potentially far-reaching implications of this rule.

**Response:**

For information on South Carolina, see the preamble to today's rule, in particular section V.B., Which States and Territories are Included in Today's Rule?

## Issue: State Background

**Organization Name:** American Society for Microbiology

**Document ID:** 162

**Comment ID:** 215

**Comment:**

The ASM is the largest single life science society with more than 42,000 members, including scientists in academic, industrial, clinical, and government institutions, working in areas related to basic and applied research, the prevention and treatment of infectious diseases, laboratory and diagnostic medicine, the environment, and water and food safety.

**Organization Name:** Association of Metropolitan Sewerage Agencies

**Document ID:** 227

**Comment ID:** 281

**Comment:**

The Association of Metropolitan Sewerage Agencies (AMSA) is pleased to offer the following comments on the U.S. Environmental Protection Agency's (EPA or Agency) proposed rule, *Water Quality Standards for Coastal and Great Lakes Recreation Waters* (July 9, 2004; 69 Fed. Reg. 41720). AMSA commends EPA for taking action to comply with the mandates under the Beaches Environmental Assessment and Coastal Health (BEACH) Act of 2000, and for the Agency's continuing commitment to improving the quality of our nation's beaches.

Over the past three years, AMSA has commented on several related EPA actions. These include EPA's May 2002 draft implementation guidance<sup>1</sup> for the 1986 bacteria criteria, which still is not final. AMSA's comments on those Agency efforts remain valid today, especially as they regard the 1986 criteria values themselves and our concerns with the lack of EPA-approved test methods for *E. coli* and enterococci. In addition to the implications of changing the indicator organisms for measuring bacteria levels, EPA's July 9 proposed rule is of particular interest to AMSA's members because it interprets the term "single sample maximum" and clarifies how it is intended to be used under the 1986 bacteria criteria.

**Footnote:**

<sup>1</sup> Implementation Guidance for Ambient Water Quality Criteria for Bacteria, May 2002 Draft, EPA-823-B-02-003

**Organization Name:** California Stormwater Quality Association

**Document ID:** 202

**Comment ID:** 126

**Comment:**

On behalf of the California Stormwater Quality Association (CASQA), thank you for the opportunity to provide comments on the Proposed Rule for Water Quality Standards for Coastal and Great Lakes Recreation Waters. CASQA is composed of stormwater quality management organizations and individuals, including cities, counties, special districts, industries, and consulting firms throughout the state, and was formed in 1989 to recommend approaches to the State Water Resources Control Board (State Water Board) for stormwater quality management in California. In this capacity, we have assisted and continue to assist the State Water Board with the development and implementation of stormwater permitting processes. Our comments are organized to address issues identified by USEPA in the proposed rule.

**Organization Name:** Chesapeake Bay Foundation

**Document ID:** 231

**Comment ID:** 164

**Comment:**

CBF is the largest non-profit organization dedicated to the protection and restoration of the Chesapeake Bay, its tributaries, and its resources. With the support of over 116,000 members, our staff of scientists, attorneys, educators and policy specialists work to ensure that changes in policy, regulation, and legislation are protective of the quality of the Chesapeake Bay and its watershed.

**Organization Name:** Department of Environmental Services City and County of Honolulu

**Document ID:** 235

**Comment ID:** 294

**Comment:**

We also submit other comments on single sample maximums, categories of coastal recreation waters, water column depths where the criteria apply and adoption of EPA approved State criteria prior to APA rulemaking.

**Organization Name:** Florida Department of Environmental Protection

**Document ID:** 229

**Comment ID:** 74

**Comment:**

The Florida Department of Environmental Protection appreciates the opportunity to provide the following comments on the Water Quality Standards for Coastal and Great Lakes Recreation Waters, Proposed Rule which was published in the Federal Register on July 9, 2004.

Comments were requested on the following topics:

1. The acceptable illness rate for fresh waters,
2. The interpretation of "as protective of human health as" the 1986 criteria,
3. The role of Single Sample Maxima,
4. High bacteria levels due to wildlife sources,
5. EPA's characterization of Florida's current status of water quality standards for coastal recreation waters, and
6. Compliance schedules.

**Organization Name:** Florida Department of Health

**Document ID:** 230

**Comment ID:** 12

**Comment:**

We have used the single sample maximum (SSM) of 104 enterococci in Florida for a number years to post advisories and alert the bathing public to water of poor quality at public marine beaches. We used a strict interpretation of the 1986 and 1994 EPA documents to conclude that a public advisory was warranted when the SSM was exceeded. In August of 2002, we increased our sampling from biweekly to weekly and subsequently established the geometric mean standard of 35 colonies/100mL. We issue advisories to the bathing public at 305 marine beaches based upon



these two standards. We also use a fecal coliform to issue warnings. Neither warnings nor advisories are "beach closings", they are only advice to the public the water is currently unfit and swimming is discouraged. At this time, we plan to continue to use the 35 geometric and 104 SSM criteria, and will not use the four separate use categories.

Web site data is available for the public and you at  
<http://apps3.doh.state.fl.us/env/beach/webout/default.cfm>

**Organization Name:** Hampton Roads Sanitation District

**Document ID:** 220

**Comment ID:** 227

**Comment:**

The Hampton Roads Sanitation District (HRSD) is pleased to provide comments on the 40 CFR Part 131 Water Quality Standards for Coastal and Great Lakes Recreation Waters; Proposed Rule published in the Federal Register on Friday, July 9, 2004 (pp. 41720-41743).

In addition to the comments submitted below, the HRSD also endorses comments submitted by the Association of Metropolitan Sewerage Agencies regarding this proposed rule.

**Organization Name:** Jeffrey A. MacDonald

**Document ID:** 177

**Comment ID:** 46

**Comment:**

I have over twenty years experience monitoring effluent from large wastewater dischargers into the Great Lakes. I have been involved with the development and implementation of beach monitoring programs in Wisconsin (serving on a statewide task force). I have served (since the 1993 Cryptosporidiosis epidemic) as a liaison to agencies concerned with maintaining safe drinking water in Milwaukee. As a microbiologist involved with analyses of effluents and surface waters for fecal coliforms and *E. coli*, I am familiar with the benefits and drawbacks of the various microbiological indicators currently in use. I am submitting these comments as a private citizen, in the hope that EPA will promulgate a rule that is protective of public health, fair to wastewater dischargers (and the populations they serve), and flexible enough to accommodate new technologies and science as progress is made in these areas.

**Background** - Wisconsin Pollutant Discharge Elimination System (WPDES) permits have used fecal coliform as the bacteriological standard for decades. *Escherichia coli* has been determined by the US EPA to be a better predictor of health risk than is the fecal coliform group (1986 Bacteria Criteria Document). EPA at that time encouraged states to move to an *E. coli* (or enterococci) standard. Following promulgation of the currently proposed rule, it is anticipated that the Wisconsin Department of Natural Resources will begin issuing permits that use *E. coli* as the bacteriological standard.

**Organization Name:** King County Department of Natural Resources and Parks

**Document ID:** 204

**Comment ID:** 326

**Comment:**

King County Department of Natural Resources and Parks, in Washington is a regional science and technical services provider with a full service environmental laboratory and scientific staff.

We are also a Phase I Stormwater permittee and operate 3 treatment plants and an interceptor collection system that treats approximately 200 million gallons of wastewater per day. We provide wastewater treatment to the Seattle metropolitan area, which has a population of approximately 1.4 million with three treatment plants. Their discharges are to marine waters. Being located in the Pacific Northwest our whole system must cope with significant wet weather periods. Our wet season extends quite literally from October to May. Also, a portion of our system is combined.

**Organization Name:** Maryland Association of Municipal Wastewater Agencies

**Document ID:** 201

**Comment ID:** 24

**Comment:**

On behalf of the Maryland Association of Municipal Wastewater Agencies, Inc. (MAMWA), please accept the following comments on the referenced proposed rule. MAMWA comprises communities statewide that are regulated under the NPDES permit program for our domestic and wet weather (CSO and storm water) discharges.

Many of our members will be subject to the criteria which EPA is proposing in its draft rule. We write in support of the comments offered by the CSO Partnership and incorporate those comments herein. We also wish to specifically note three issues of paramount concern to communities across Maryland.

**Organization Name:** Massachusetts Water Resources Authority

**Document ID:** 245

**Comment ID:** 172

**Comment:**

MWRA provides wholesale water and sewer services in service areas encompassing, in whole or in part, 61 communities in Massachusetts, including most of the metropolitan Boston area. 43 communities connect their local sewer systems, some of which are combined sanitary and storm sewers, to MWRA's regional sewage collection and treatment facilities. Approximately 2.6 million people, or approximately 43 percent of the total population of Massachusetts, live in MWRA's service areas. MWRA's wastewater treatment facility is the second largest facility in the country.

**Organization Name:** Michael Doran Techknowledge

**Document ID:** 209

**Comment ID:** 149

**Comment:**

I have over thirty years of experience in the water quality protection field. Currently I serve as a representative of the Wisconsin Section of the Central States Water Environment Association (part of the Water Environment Federation) to a Technical Advisory Committee formed by the Wisconsin Department of Natural Resources for the purpose of recommending new bacterial water quality standards for Wisconsin waters.

**Organization Name:** Municipal Environmental Group

**Document ID:** 225

**Comment ID:** 81

**Comment:**

We are submitting these comments on behalf of the Municipal Environmental Group's Wastewater Division ("MEG"). MEG is an association of approximately 90 Wisconsin municipalities throughout the state that own and operate wastewater treatment facilities. MEG writes today to express its strong opposition to the proposal to develop federal criteria in lieu of well-planned state criteria.

We currently serve on the state committee that is developing bacteria water quality standards for Wisconsin waters. That committee has been working diligently to develop criteria that recognize the specific needs and circumstances of waters in this state.

**Organization Name:** NRDC, Clean Water Project

**Document ID:** 192

**Comment ID:** 203

**Comment:**

The Natural Resources Defense Council (NRDC) is pleased to submit these comments on the US EPA's proposed pathogen water quality standards. These proposed rules were published July 9, 2004 in the Federal Register, 69 Fed. Reg. 41720, and would be codified at 40 C.F.R. at 131.41.

EPA proposes to promulgate standards for states that have not yet adopted pathogen criteria consistent with the Beaches Environmental Assessment and Coastal Health Act of 2000 (BEACH Act). The BEACH Act amended the Clean Water Act (CWA), requiring the states to develop new water quality standards for coastal and recreational waters consistent with the US EPA's CWA Section 304(a) pathogen criteria developed in 1986. States were to have adopted these criteria by April 10, 2004. For the states that have not complied with this deadline, EPA is under a mandatory duty to "promptly promulgate" regulations. 33 U.S.C. at 1313(i)(2)(A).

NRDC supports EPA's decision to promulgate of standards as consistent with its mandatory duty under the statute. NRDC is, however, opposed to certain specific components of the rule. NRDC asks the EPA to modify this proposed rule consistent with these comments and promptly proceed with promulgation of a final rule for those states that continue to lack adequate standards. As four months have already elapsed since the statutory deadline for states to have adequate pathogen criteria in place, NRDC encourages the EPA to move forward promptly.

**Organization Name:** Northeast Ohio Regional Sewer District

**Document ID:** 198

**Comment ID:** 303

**Comment:**

In addition to the comments submitted below and in the attachments, the NEORSD also endorses comments submitted by the Association of Metropolitan Sewerage Agencies regarding this proposed rule.

**Organization Name:** South Carolina Water Quality Association

**Document ID:** 200

**Comment ID:** 14

**Comment:**

On behalf of the South Carolina Water Quality Association, please accept the following comments on the referenced proposed rule. The SC WQA comprises communities statewide that

are regulated under the NPDES permit program for our domestic and wet weather (storm water) discharges.

Many of our members will be subject to the criteria which EPA is proposing in its draft rule. We write in support of the comments offered by the CSO Partnership and incorporate those comments herein. We also wish to specifically note three issues of paramount concern to communities in South Carolina.

**Organization Name:** State of Louisiana Department of Environmental Quality

**Document ID:** 171

**Comment ID:** 168

**Comment:**

Thank you for your letter of April 19, 2004, in which the Louisiana Department of Environmental Quality (LDEQ) is reminded of the current BEACH Act deadline for adopting the EPA's 1986 bacteria criteria. The LDEQ continues to work diligently towards incorporation of appropriate pathogen indicators into the State's water quality standards to protect designated uses and improve public health protection for Louisiana's coastal recreation waters and beaches.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 343

**Comment:**

We are enclosing lengthy comments on the draft rule for your consideration. Please consider these comments in addition to the technical material that we have already sent for your review and are referenced in the draft rule. The following summarizes some of our key comments:

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 356

**Comment:**

While Washington finds significant fault with, and thus opposes, the draft federal rule, we support the overall goal of protecting water contact recreation and meeting the goals of the federal Clean Water Act. Our comments, while critical of the current proposal, are intended to assist EPA in developing a strong final regulation should it choose to continue toward that objective. Washington remains committed to providing a high degree of protection for all of its waters, and will continue to set strong standards to protect the health of its citizens. We look forward to continuing to work with EPA in partnership to ensure that the water quality standards used to protect our nations waters have a solid foundation and that we are all moving together towards meeting the goals of the Act.

**Organization Name:** Surfrider Foundation

**Document ID:** 194

**Comment ID:** 116

**Comment:**

These comments on the proposed rule, *Water Quality Standards for Coastal and Great Lakes Recreation Waters*, are being submitted on behalf of the Surfrider Foundation. The Surfrider Foundation is a grassroots, non-profit, environmental organization that works to protect our

oceans, waves, and beaches. Surfrider Foundation now has over 37,000 members in the United States. For over 10 years, Surfrider Foundation members have been conducting water quality monitoring at ocean beach locations along the West, East and Gulf coasts as part of our Blue Water Task Force (BWTF) program. This program was a precursor to the monitoring requirements of section 303(i) of the Clean Water Act and, along with other efforts by Surfrider Foundation and other environmental groups, helped spur passage of the "Beach Bill" in October 2000. Our BWTF program has become an integral part of the recreational water quality monitoring program in several jurisdictions, including Oregon, Washington, and San Mateo County, California.

**Organization Name:** The CSO Partnership

**Document ID:** 197

**Comment ID:** 402

**Comment:**

On behalf of the CSO Partnership, please accept the following comments on the referenced proposed rule. The CSO Partnership comprises communities across the nation, primarily small and medium-sized, that are striving to minimize CSO discharges in accordance with the Clean Water Act and the National CSO Control Policy.

The mission of the CSO Partnership is to build and sustain a coalition between federal, state, and local governments and environmental organizations to promote federal legislative, regulatory and policy initiatives and adequate funding to ensure the development and implementation of cost-effective and affordable environmental controls to abate or minimize the negative impacts of combined sewer overflows (CSOs) on our nation's receiving waters. The goals of the CSO Partnership are to assure the adoption of legislative and regulatory policies and guidance that result in cost-effective, site-specific criteria that assist towns and cities in controlling their CSOs to protect our nation's water bodies. In pursuit of these goals we offer the following comments on the proposed rule.

**Response:**

EPA appreciates the commenters providing this background information.

EPA acknowledges the comment encouraging EPA to promulgate a rule that is protective of public health, fair to wastewater dischargers, and flexible enough to accommodate new technologies and science. EPA believes that it has done so with today's rule. The rule protects human health at the levels specified by the 1986 bacteria criteria document. The rule specifically recognizes that the rules of general application that are found in State and Territory water quality standards apply to the criteria promulgated in the rule. EPA also provides a discussion of the flexibility that States and Territories have in implementing the promulgated criteria. EPA notes that it cannot forecast all developments in technology and science, but EPA is considering new technologies and science as EPA develops new water quality criteria for pathogens and pathogen indicators as required by Clean Water Act section 304(a)(9).

## Issue: State Flexibility

**Organization Name:** American Forest and Paper Association

**Document ID:** 191

**Comment ID:** 193

**Comment:**

EPA ought to encourage and provide the flexibility and guidance for States to implement approaches that are more effective in directly assessing and controlling the real threats to human health. This particularly is important to minimize wasting scarce agency and regulated community resources when potential false positives are suspected.

**Organization Name:** County of Orange, CA/RDMD/Watershed and Coastal Resources Division

**Document ID:** 193

**Comment ID:** 181

**Comment:**

The variety of use at California beaches is unique to the state, and such designation decisions should be made on local information.

**Organization Name:** Oregon Department of Environmental Quality

**Document ID:** 174

**Comment ID:** 61

**Comment:**

DEQ believes it is beneficial to have both a geometric mean value and single sample maximum value included in the final rule, but DEQ would like to retain its right to develop its own distributions and to designate the intensity of beach usage that corresponds to the single sample maximum. Furthermore, DEQ believes that States should have the option of designating whichever use level is appropriate to its waters. The current Oregon water quality standard for the single sample maximum for *E. coli* in fresh water is based on the "lightly used" designation. Oregon Health Services uses the "moderate" category in implementing the Beach Monitoring and Advisory program in marine waters.

**Organization Name:** Oregon Department of Environmental Quality

**Document ID:** 174

**Comment ID:** 68

**Comment:**

EPA should consider including rule language that incorporates freshwater influence during storm events. DEQ considered data from the early 1990s when it last evaluated its bacteria criteria. DEQ believes that EPA should allow states some flexibility on how to apply the single sample maximum for the purposes of compliance in NPDES permits. The Oregon Administrative Rules (OAR Chapter 340, Division 41) contain language that states: "No violation will be found for an exceedance under this paragraph if the permittee takes at least five consecutive re-samples at four hour intervals beginning as soon as practicable (preferably within 28 hours) after the original sample(s) were taken..."

and

"The Commission may on a case-by-case basis approve a bacteria control management plan to be prepared by the permittee, for a basin or specified geographical area which describes hydrologic conditions under which the numeric bacteria criteria would be waived. These plans will identify the specific hydrologic conditions; identify the public notification and education processes that will be followed to inform the public about an event and the plan; describe the water quality assessment conducted to determine bacteria sources and loads associated with the specified hydrologic conditions; and describe the bacteria control program that is being implemented in the basin or specified geographical area for the identified sources."

**Organization Name:** Pennsylvania Department of Environmental Protection

**Document ID:** 233

**Comment ID:** 250

**Comment:**

As your agency formulates a final rule for Water Quality Standards for Coastal and Great Lakes Recreation Waters, we urge you to work closely with the states' water quality and beach protection programs and to foster better coordination between EPA's Regional Water Quality Standards and Beaches Programs to design a rule that allows the states maximum flexibility and provides explicit discretion to implement programs that address case-specific concerns and needs when necessary. To date, this program coordination has been lacking or inadequate.

**Organization Name:** Pennsylvania Department of Environmental Protection

**Document ID:** 233

**Comment ID:** 257

**Comment:**

States should have considerable discretion in defining each of the usage categories based primarily on regional and geographical expectations for the type of waterbody in question. One size does not and will not fit all. The use intensity must be relative to the state's comparison of frequency of use for similar areas, similar waters, and similar swimming season parameters such as, but not limited to, public access / availability, weather / climatic conditions, and the public / bathing community's preferences and desires for particular recreational experiences.

**Organization Name:** Pennsylvania Department of Environmental Protection

**Document ID:** 233

**Comment ID:** 263

**Comment:**

States should be allowed discretion on establishing policies and procedures when and/or if permits are to be opened or modified for new limits during an existing permit term. States should be allowed to continue on the normal schedule to re-issue permits, which may also include a compliance schedule, if needed.

**Organization Name:** People for Puget Sound

**Document ID:** 242

**Comment ID:** 32

**Comment:**

We urge you to both reconsider your approach and to allow state's the ability to utilize more protective criteria if they see fit to do so.

**Organization Name:** South Carolina Department of Health and Environmental Control Bureau of Water

**Document ID:** 161

**Comment ID:** 219

**Comment:**

While we believe the standard should contain both a geometric mean and an SSM, we support EPA's options that offer states flexibility in deciding which SSM applies to which waters. In our State, we can easily determine which beaches are "designated swimming areas" because of amenities like lifeguards, ready public access, and they are a great tourist draw. We have also used this designation for coastal recreational waters that have our highest water quality classifications. For these we have used the SSM at the 75% confidence level. All other coastal recreational waters, typically less accessible and shallower tidal creeks, have the SSM at the 95% confidence level. We believe this is protective of South Carolina's coastal recreational waters. All states should have this same option.

**Organization Name:** State of Hawaii Department of Health/Environmental Health Administration

**Document ID:** 195

**Comment ID:** 401

**Comment:**

**The State's Preferred Options**

DOH reserves its rights to develop state rules that differ from the preferences stated above. State rule making will give Hawaii's people a better chance to express their preferences.

**Organization Name:** State of Louisiana Department of Environmental Quality

**Document ID:** 171

**Comment ID:** 169

**Comment:**

While the EPA's current draft guidance has emphasized states' flexibility in the bacteria criteria development process, we are also aware that this guidance has not been finalized pending a decision on policy review. As the next target date of your Clean Beach Plan<sup>2</sup> approaches, we would like to emphasize that flexibility is of critical importance in order for bacteria criteria to be implemented in a meaningful way in Louisiana.

**Footnote:**

<sup>2</sup> On April 19, 2004, Acting Assistant Administrator for Water, Benjamin H. Grumbles announced the Bush administration's Clean Beaches Plan. This Plan is designed to accelerate progress at the federal and state level to meet the requirements of the BEACH Act of 2000 that requires coastal states, including Louisiana, to adopt 304(a) pathogen criteria into the water quality standards by April 10, 2004. The Act provides that, if a state fails to meet this deadline, EPA must promptly propose Federal standards to protect that state's beaches. To date, only 11 of the 35 affected states and territories have adopted up-to-date criteria for pathogens. By June 30, EPA will propose Federal revised standards for pathogens for the states and territories that have not yet done so.



**Organization Name:** State of Ohio Environmental Protection Agency

**Document ID:** 238

**Comment ID:** 130

**Comment:**

We understand the technical reasons for including Ohio in the proposed rule. Ohio EPA is planning our own rulemaking to revise the water quality standards for protection of recreational uses. However, it is unlikely that Ohio EPA's rulemaking will take place prior to completion of the federal promulgation. We intend to draw upon the federal rule and its discussion of a number of implementation topics that were not addressed in the 1986 federal bacteria guidance. There are options currently under consideration for a number of topics of concern to states, such as use of the single sample maximum, calculation of site-specific single sample maximums, subcategorization of recreational uses, and nonhuman sources of fecal contamination. While Ohio EPA is not offering specific comments on those topics, we advocate adoption of rule language that provides states flexibility in addressing those topics within their own water quality standards.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 363

**Comment:**

Washington does not concur with the statement that states have broad discretion in designating uses. This may be a true statement for some EPA regions but certainly not in ours. The reality is that EPA remains very resistant to allowing primary contact uses to be removed from waters (as well as any other use), and that the federal rules require that such waters be considered in noncompliance with the goals of the Act. This statement gives the impression that states can simply limit the applicability of the federal rule by changing designated uses; which we believe is incorrect.

**Organization Name:** Tri-TAC

**Document ID:** 223

**Comment ID:** 431

**Comment:**

Under the discussion of Alternative Regulatory Approaches and Implementation Mechanisms, Tri-TAC supports flexibility for States to develop additional categories of recreation uses. In particular, Tri-TAC urges EPA to develop guidance documents and policy statements that can assist States in developing appropriate uses, subcategories of uses and standards for wet-weather conditions.

**Response:**

EPA would like to remind commenters that with promulgation of this rule, States and Territories will still retain the ability to adopt *E. coli* or enterococci criteria that are more protective than those published in the final rule. Additionally, EPA has provided flexibility to states in several aspects of the final rule; please see the preamble to the final rule, especially sections IV.B.3., Use of the Single Sample Maximum; IV.B.4., Intensity of Use Categories of Coastal Recreation Waters; and IV.B.6., State Calculation of Single Sample Maximums. Also, more information on designating uses and use attainability analyses is in the preamble to the final rule at section VII., Alternative Regulatory Approaches and Implementation Mechanisms.

## **Issue: States' and Territories' Current Standards**

**Organization Name:** Northeast Ohio Regional Sewer District

**Document ID:** 198

**Comment ID:** 470

**Comment:**

Additionally, samples taken to characterize particular events might not be reported with other regular samples and should not be used by water quality management authorities in calculations of geometric means for the beach in question. Note that, while they would not be reporting this research data, they would be using this data to support the provision of alerts to the beach-going public.

While the situations of this particular beach and the described management strategy may be somewhat unique, it is likely that many beaches have their own unique factors which, when better understood, can lead to the development of management strategies that are protective of public health. The final rule would ideally encourage these additional studies and should be particularly careful not to develop measures that penalize better understanding of the factors affecting risks to public health.

**Response:**

EPA appreciates the comments on suggestions on a better monitoring strategy at beaches. However, this comment addresses a concept outside of the scope of today's rule which does not establish requirements for beach monitoring.

## **Issue: Tribal Waters and CWA Section 303(I)**

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 387

**Comment:**

While it is relatively clear EPA can exclude tribal waters, the federal rule seems like an appropriate venue to discuss how EPA will ensure that the lack of tribal standards will not result in a lack of protection for coastal recreation waters under the tribes' jurisdictions. It does after all, seem illogical for EPA to take the position that a total lack of any criteria in tribal waters is justification not to assign federal criteria, but the presence of state criteria that do not exactly match the federal recommendations is justification.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 391

**Comment:**

As Washington was developing its recently revised bacterial criteria, tribal governments expressed significant concern that the use of the EPA recommended criteria would demonstrably risk the shellfish resources of the state to which they have a legal right. They were also concerned that using the recommended EPA criteria would result in a general lowering in the quality of water for ceremonial purposes. EPA is encouraged to contact the coastal and Puget Sound tribes directly to engage in government-to-government consultations over the impact of the federal rule on their treaty rights.

**Response:**

See the preamble to today's rule, in particular section V.B.

In addition, EPA works with tribal authorities on a regular basis to ensure that issues of concern to Tribes are considered in Agency decisions. EPA has contacted those Tribes identified as having coastal or Great Lakes waters to inform them of the potential future impact this rule could have on Tribal waters.

EPA does not expect the quality of coastal recreation waters to be lowered as a result of this rulemaking. This rule does not alter the existing fecal coliform criteria for shellfish: in coastal recreation waters that are also designated for shellfishing, both fecal coliform criteria to protect shellfishing uses and *E. coli* or enterococci criteria to protect primary contact recreation uses would apply. EPA recognizes that tribes may use their waters differently than the recreational uses described in today's rule, such as for ceremonial uses. However, because *E. coli* and enterococci are better indicators of immersion-related risk than fecal coliforms, EPA expects that any change from fecal coliform criteria to *E. coli* or enterococci criteria to protect uses involving immersion in those waters would result in better protection because *E. coli* and enterococci are better predictors of illness than fecal coliforms.

As explained in section V.A.1. of the preamble, EPA considers the information provided by the Washington Department of Ecology to show that use of the Washington fecal coliform criterion of 14/100 ml will result in enterococci concentrations below EPA's criterion in Washington's coastal recreation waters. Also, use of the Washington fecal coliform criterion of 14/100 ml could result in instances when the State of Washington would close a beach or issue a beach advisory

when the enterococci concentrations are below the EPA criterion. For this reason, EPA has determined that use of the Washington fecal coliform criterion of 14/100 ml to protect recreational uses would be as protective of human health as use of EPA's enterococci criterion in Washington's coastal recreation waters, as explained in section V.A.1. of the preamble.

**Issue: UAA****Organization Name:** Pennsylvania Department of Environmental Protection**Document ID:** 233**Comment ID:** 258**Comment:**

PA DEP would like EPA to continue its efforts to address the states' concerns related to conducting use attainability analyses (UAAs) for recreational waters. We believe that states should be able to establish subcategories of recreational uses by allowing categorical UAAs for waterbodies based on the waterbody type(s) and recreational use intensity. Therefore, we request that EPA provide additional guidance on this issue which should continue to be addressed in the draft implementation guidance that EPA was developing along with the States' and ASIWPCA's involvement prior to this rulemaking.

**Response:**

EPA recognizes that States can establish sub-categories of their designated uses. When doing so, the State would need to comply with the Clean Water Act and 40 CFR 131(10)(j)(2) and conduct a use attainability analysis where the state is removing a use specified in section 101(a)(2) of the CWA or where adopting sub-categories of uses that require less stringent criteria.

EPA is currently working with States to identify best practices for use attainability analysis development.

## Issue: Washington

**Organization Name:** King County Department of Natural Resources and Parks

**Document ID:** 158

**Comment ID:** 268

**Comment:**

In my state of Washington, the State Department of Ecology has already completed a standards revision had been kept from implementing it due to the EPA consultation and review of those new standards which has already extending more than a year. The extended review was caused by temperature standard comments, not on the bacterial standards as far as we know. There is significant documentation of the reasons for WA to concluded that the State would be at least as protective and in some cases more protective with the FC standards adopted than the proposed Enterococcus proposed for the marine waters.

**Organization Name:** King County Department of Natural Resources and Parks

**Document ID:** 158

**Comment ID:** 270

**Comment:**

Further, Washington State adopted (and are awaiting concurrence from EPA along with concurrence on the bacterial standards) use based standards last July. Since you rule says that "...EPA will review used designations adopted by the states..."(pg. 41735), we must also comment to EPA on the used based standards issue.

**Organization Name:** King County Department of Natural Resources and Parks

**Document ID:** 204

**Comment ID:** 328

**Comment:**

In 2002 Washington State completed a multi-year evaluation of the state's standards, including consideration of enterococcus for marine waters. After extensive study of current epidemiological information, the costs and other issues with changing to this approach, they adopted a hybrid approach of retaining very low fecal coliform (FC) standards for primary contact recreation, and enterococcus for secondary contact. We feel this approach is protective an appropriate and should be considered approval by EPA. It has also been our experience that maintaining the low FC standards for primary contact in Washington waters has been effective (no disease incidences have been reported).

**Organization Name:** King County Department of Natural Resources and Parks

**Document ID:** 204

**Comment ID:** 330

**Comment:**

Scientists across the country and around the world have argued the technical merits and shortcomings of replacing the FC standard with enterococcus. It appears EPA has not accepted these arguments. Our understanding of the rational is that the predictive value of enterococcus provides a better safeguard against illness when swimming (total head submersion) at a recreational water site. The purpose of these comments, at this point, is not to point out the shortcomings of the studies that EPA has used to defend its position. Rather, we wish to point out some of the pragmatic issues facing the laboratories, operators and environmental scientists who

will have to implement any new regulatory tool. While we agree that enterococcus and *E. coli* serve as better correlates to the incidence of disease in swimmers, we do not believe that switching the water quality standard for all marine waters in Washington State (and perhaps more waters in the future) is a scientifically reasonable nor economically appropriate action at this time.

**Organization Name:** Pacific Coast Shellfish Growers

**Document ID:** 164

**Comment ID:** 70

**Comment:**

The EPA has included Washington, Alaska, California and Oregon in this rule without adequately researching or addressing the current fecal coliform standards in place in these states for protecting shellfish growing waters - a far stricter standard than the one proposed by EPA for swimming waters.

The EPA's finding that these states do not have in place criteria "as protective of human health as EPA's 1986 recommended bacteria criteria" is premature, given that EPA has not fully evaluated criteria to make this determination. Washington State has submitted data to EPA that demonstrates this equivalency, yet EPA has failed to analyze it, to-date, as noted in the Rule: *"EPA is reviewing this information...and has not yet determined that the data demonstrate that Washington's standards satisfy the requirements of section 303(i)."* EPA further states it has *"conducted a preliminary review of the water quality standards for all states in question..."* and further notes they are continuing to *"solicit comment to confirm whether EPA has accurately characterized the current status of water quality standards..."*

A fecal coliform concentration of 14/100 ml is a stricter standard than EPA's recommended enterococci criteria of 35/100 ml. The West Coast (and all other shellfish producing) states' 14/100 ml fecal standards will meet the 35/100 enterococci standards, while the enterococci standard will fail to meet the fecal coliform standard that is required under the National Shellfish Sanitation Program (NSSP), under the Food and Drug Administration, for management of shellfish growing areas. As noted above, Washington has submitted data which demonstrated the use of fecal coliform at 14/100 ml is more protective than EPA's proposed enterococci standard, yet EPA has not yet analyzed this information.

**Organization Name:** People for Puget Sound

**Document ID:** 242

**Comment ID:** 31

**Comment:**

Thank you for the opportunity to comment on the proposed EPA bacteria criteria rule. This is a topic that has been discussed and debated in Washington state for the past several years. We are very concerned that the proposed federal rule will utilize an approach which is less sensitive and less protective of water quality than the one taken by Washington state.

**Organization Name:** People for Puget Sound

**Document ID:** 242

**Comment ID:** 33

**Comment:**

Our principal concern has to do with the decision to shift from a fecal coliform standard to enterococci standard. Data that we have reviewed leads us to believe that this approach would allow for higher allowable bacteria levels and, as such, more illnesses among those who work and recreate in marine waters. The data, which was submitted to your office by the Washington Department of Ecology, shows that the state's 14 per 100 milliliter fecal coliform organism standard is more protective than the 35 per 100 milliliter enterococci organism standard that you are proposing to use.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 340

**Comment:**

Our analysis of paired fecal coliform and enterococci sample data (supplied previously to EPA Region 10 and EPA headquarters staff) demonstrates that a fecal coliform criterion of 14/100 ml is more restrictive of bacterial pollution than an enterococci concentration of 35/100 ml. Waters meeting the 14/100 ml criteria will also meet the 35/100 ml enterococci recommendation. This greater level of protection is coupled with significantly reduced costs for our state and its cooperators.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 345

**Comment:**

EPA should recognize low concentrations of fecal coliform are equally protective.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 357

**Comment:**

**Washington Should be Removed from the Final Rule**

The state of Washington was disappointed to find itself included in the draft federal regulation applying enterococci criteria to its marine waters. We have been in discussions with EPA Region 10 and EPA headquarters for many years regarding our recent revisions to our state's bacterial standards. That review culminated in our retaining the use of the shellfish harvesting criteria (a fecal coliform geometric mean of 14/100 ml) in all marine waters designated for primary contact recreation. Our analysis of paired fecal coliform and enterococci sample data (supplied previously to EPA Region 10 and EPA headquarters staff) demonstrates that a fecal coliform criteria of 14/100 is more restrictive of bacterial pollution than an enterococci concentration of 35/100 ml. In addition, waters meeting the 14/100 ml criteria also meet the 35/100 ml enterococci recommendation. Based on a regression analysis, the fecal coliform concentration of 14/100 ml is roughly equivalent to an enterococci concentration of 20/100 ml. This greater level of protection is coupled with significantly reduced costs for our state and its cooperators.

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 382



**Comment:**

Washington has chosen recently to continue to use fecal coliform at concentration levels well below the former EPA recommendations. The fact that fecal coliform is being used does not serve as a defensible demonstration that the criteria are not protective. In our waters, a fecal coliform concentration of 14/100 ml is more stringent and thus more protective than enterococci criteria of 35/100 ml. Waters meeting the 14/100 ml fecal standards will also meet the 35/100 enterococci standard. However, waters meeting the 35/100 enterococci standard will be in violation of the fecal coliform criteria approximately 20 percent of the time (based on single sample comparisons). While we are not suggesting that enterococci is a poor indicator, we are suggesting and have provided the data to reasonably demonstrate that a fecal coliform criteria set a low concentration level provides better protection for public health in our state. It also allows for less complicated criteria for the public and cooperators to understand, and saves a great deal of money by not requiring governmental agencies and businesses to analyze samples unnecessarily for both fecal coliform (to protect shellfish) and enterococci (to protect swimming).

**Organization Name:** State of Washington Department of Ecology

**Document ID:** 243

**Comment ID:** 385

**Comment:**

As noted in the draft rule, the state of Washington has submitted data demonstrating that the use of fecal coliform at 14/100 ml is more protective than the use of enterococci at 35/100 ml. If EPA is interested, we will also submit data demonstrating that in our state's fresh waters *E. coli* has nearly a 1:1 correlation with fecal coliform. Thus using any fecal coliform criteria equal or less than *E. coli* is also more protective than the federal guidelines. We understand that EPA wants states to adopt the EPA preferred indicators, but where a state such as Washington can reasonably demonstrate they are using alternative criteria that are actually more protective, EPA is obligated not to include them in a federal rule. Washington's decision to continue to use fecal coliform was not based on a desire to avoid changing indicators, but based on a scientific assessment of the protection our criteria provides and the social and economic costs of changing indicators. There are substantial financial costs associated with requiring governmental and private labs to set up to analyze for enterococci. In addition, the need to continue to meet shellfish criteria means that many governmental and private entities will need to sample and conduct laboratory analyses for two to three indicators (three if the freshwater criteria is *E. coli* and the downstream marine water has criteria for both fecal coliform and enterococci).

**Response:**

See the preamble to today's rule, in particular section V.A.

EPA disagrees with the comments that the costs associated with switching from a fecal coliform criteria to an enterococci criteria, including the need at times for entities to monitor for both fecal coliform and enterococci. EPA notes that today's rule does not establish minimum monitoring requirements for enterococci. States have the flexibility to develop monitoring programs that meet their needs, including monitoring for beach closure as well as for shellfish harvesting and non-swimming recreational purposes. If a State opts to monitor for both fecal coliform and enterococci, EPA expects that the incremental costs of the samples would be relatively low. Washington Department of Ecology estimated analytical costs of \$20 for fecal coliform and \$29 for enterococci in their cost analysis of their 2003 triennial standards review. With respect to the State of Washington, EPA expects the actual cost of dual monitoring to be small because the Washington Department of Ecology and Department of Health currently are monitoring beaches

and are sampling all for enterococci in addition to the normal monitoring for fecal coliform, as described on their website.

EPA disagrees that the regression conducted between fecal coliform and enterococci show that when fecal coliform concentrations are at 14/100 ml, the enterococci concentrations are about 20/100 ml. The Washington Department of Ecology did not provide the specifics of this regression analysis, so EPA attempted to recreate it from the data provided. EPA looked at geometric mean concentrations, which are the basis of the Washington water quality criterion. EPA also looked at data for the summer period, when people are most likely to become immersed in water, and for nearshore shallow locations, where people are most likely to be in the water. From these data, EPA conducted a regression analysis and found a correlation coefficient of 0.48. This means that less than half of the variability in enterococci concentrations could be explained by the fecal coliform concentrations. EPA does not consider this sufficient to use specific fecal coliform concentrations to predict specific enterococci concentrations. However, EPA does consider use of the Washington fecal coliform criterion of 14/100 ml to protect recreational uses would be as protective of human health as use of EPA's enterococci criterion, as explained in section V.A.1. of the preamble.

EPA disagrees with the comment that switching the water quality standard for all marine waters in Washington State is neither scientifically reasonable nor economically appropriate action at this time. EPA believes that the scientific basis of the criterion is reasonable, and that the flexibility for a State to show that its existing criteria are as protective of human health provides a mechanism for a State to use other scientifically reasonable criteria, as long as the criteria are as protective as EPA's criteria. EPA also disagrees that the rule is economically inappropriate. The commenter did not provide any information or data to support the claim that the rule is not an economically appropriate action at this time. Regardless, EPA estimated the costs of this rule and determined that the rule will not impose any undue economic hardship on affected entities. EPA estimates the total annual costs to municipal and nonmunicipal dischargers to be approximately \$20 million. EPA estimates that Americans take a total of 910 million trips to coastal areas each year and spend about \$44 billion at those beach locations.

EPA agrees with the comment that enterococcus and *E. coli* better correlates to the incidence of disease in swimmers.